

**EVALUATION OF POSITIVE EXPIRATORY PRESSURE (PEP)  
DEVICES AS AN ADJUNCT TO CARDIO-RESPIRATORY  
PHYSIOTHERAPY IN PATIENTS FOLLOWING OPEN ABDOMINAL  
SURGERY**

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JCBREN005

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

In fulfillment of the requirements for the degree

MSc Physiotherapy

Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

Division: Physiotherapy

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Date of submission: 7 April 2015

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## DECLARATION

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## ABSTRACT

Purpose: Cardio-respiratory physiotherapy for patients undergoing abdominal surgery has been found to be beneficial in improving lung function post-operatively and in the prevention and treatment of post-operative pulmonary complications (PPCs). The Blow Bottle, a Positive Expiratory Pressure (PEP) therapy device, is commonly used as an adjunct to physiotherapy. The Blow Bottle is low cost and can be easily made by the physiotherapist using readily available materials in the hospital setting. However, evidence to support the use of Blow Bottles in the post-operative management of abdominal surgery is minimal, with few studies reporting significant positive effects especially when compared to conventional cardio-respiratory physiotherapy techniques.

Methodology: A randomized control was implemented in a public tertiary institution within the Western Cape. Patients admitted for open abdominal surgery via midline incision were eligible for the trial. Participants were randomly allocated to either the control group (CG) receiving conventional post-operative cardio-respiratory physiotherapy, or the intervention group (IG) who received the additional use of the Blow Bottle. Lung function and the development of post-operative pulmonary complications were the primary outcomes of this study. Lung Function was evaluated by means of spirometry testing and interpretation of Forced Expiratory Volume in 1 second (FEV<sub>1</sub>) and Forced Vital Capacity (FVC). The development of post-operative pulmonary complications were diagnosed using the criteria by Mackay et al. (2005) where changes from pre-operative findings of auscultation; temperature, X-ray and sputum are evaluated post-operatively and recorded using the Adapted Abdominal Physiotherapy Outcomes Data Sheet (A-APODS).

Results: A total of 19 participants were enrolled in the study, n=11 (CG) and n=8 (IG), predominantly female (n=14) and admitted for cancer related abdominal surgery (n=9). There was a statistically significant ( $p<0.05$ ) marked reduction in post-operative lung function from baseline across groups, 62% in FEV<sub>1</sub> and 47% in FVC on the first post-operative day. The FEV<sub>1</sub> and FVC were similar across both the control and intervention groups for the first three post-operative days. On auscultation majority of participants had decreased breath sounds on the first post-operative day. However, no one participant developed a PPC across the duration of the study as diagnosed using the criteria by Mackay et al. (2005).

Conclusion: Whether the additional use of the Blow Bottle is more beneficial than conventional post-operative cardio-physiotherapy alone is inconclusive due to the incremental drop out of participants from the study and small sample size. In this study there was however a significant reduction in lung function post-operatively. This mandates the need for further research investigating the abdominal surgical field and the use of devices to improve lung function, such as the Blow Bottle, as literature is scant and outdated, and sorely lacking in the resource constraint South African hospital settings.

## **DEDICATION**

To my fiancé, my rock, for always encouraging and supporting me, and keeping me sane through this challenging yet rewarding experience.

## ACKNOWLEDGEMENTS

I would like to acknowledge the following institutions and persons for the contributions they have made towards this thesis and throughout my Masters journey:

The University of Cape Town for allowing me to pursue a Master's Degree in Physiotherapy.

The National Research Fund (NRF) and the Cardio-Pulmonary Rehabilitation (CPR) Group of the South African Society of Physiotherapy (SASP) for awarding funding for this project and my tuition.

To all the hospital management, nursing staff, surgical and physiotherapy teams of the respective institutions involved in this study, namely, Constantiaberg Hospital, Kingsbury Hospital, Vincent Pallotti Hospital and Groote Schuur Hospital. Thank you for your co-operation and participation during the study.

A special thank you to the staff and physiotherapy teams of Groote Schuur hospital. To the physiotherapy department headed by Carolyn Davids and especially Sameega Salie who assisted tremendously during the data collection process, your involvement in the study and willingness to assist was greatly appreciated.

My research assistants, Zeenath Higgins, Fadia Adjerahn and Gadija Ganief for assisting daily during the data collection process. Thank you for the time and effort you put into assisting me.

Wynand Smythe and the Clinical Research Centre for all the advice and assistance with the statistical analyses.

Yvonne Thiebaut, for your patience in editing this thesis manuscript.

Most of all, to my supervisor Shamila Manie and co-supervisor Lunelle Pienaar. This Masters journey has not been without its challenges, but I thank you both very much for the time and dedication you gave to assisting me through this process. Your words of encouragement have really kept me motivated through the trying times. Your expertise and knowledge that you have imparted are much appreciated and I thank you for being with me every step of the way.

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## **CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW**

### **1.1 Background**

Open abdominal surgery is associated with reductions in lung function and diminished ability by the patient to breathe deeply and cough effectively. Both the surgery and the subsequent impairments increase the risk for the development of post-operative pulmonary complications (PPCs) such as pneumonia and atelectasis (Brooks-Brunn, 1995; Silva, Li & Rickard, 2012). The development of PPCs is associated with a prolonged hospital stay and subsequent increased costs (Tzani, Chetta & Olivieri, 2011). Cardiorespiratory physiotherapy regimes, involve the application of techniques aimed at increasing patients' post-operative respiratory and general function. In the abdominal surgical population, cardiorespiratory regimes including early mobilization and deep breathing exercises have been found to be beneficial in improving post-operative lung volumes and decreasing the risk for the development of PPCs (Manzano, Carvalho, Fernandes, Saraiva-Romanholo & Vieira, 2008; Mackay, Ellis & Johnston, 2005; Richardson & Sabanathan, 1997).

Positive Expiratory Pressure (PEP) therapy is a technique that physiotherapists can employ to assist airway clearance and improve lung function (Clini, 2009). The Blow Bottle is an example of a PEP therapy device commonly used by physiotherapists within the hospital setting (Johnston, James & Mackney, 2013; Johansson, Sjöholm, Stafberg & Westerdahl, 2013). However, the evidence for its effectiveness in the treatment of patients, following abdominal surgery, has been minimal and outdated (Johnston, James & Mackney, 2013; Johansson et al., 2013; Fiore, Chiavegato, Paisani, Colucci, 2010; Orman & Westerdahl, 2010). This research therefore serves to investigate PEP therapy in the abdominal surgical population with specific reference to the use of the Blow Bottle as an adjunct to cardio-respiratory physiotherapy.

### **Abdominal Surgery and Pulmonary Function**

Breathing is an essential task necessary to sustain life. The mechanism of breathing is achieved by the action of the respiratory muscles. The diaphragm plays a vital role in breathing as during inspiration the diaphragm muscle contracts, causing it to flatten and descend. This action thereby expands the thoracic cavity, allowing air to enter the lungs (Chuter, Weissman, Mathews, Starker, 1990; Roussos, 1985). The expiratory muscles are not usually active during breathing. However, as ventilatory demands increase or forced expiratory manoeuvres are required, as during coughing and vomiting, expiratory muscles such as the abdominal muscles become active. The action of the abdominal muscles increases intra-abdominal pressure, which allows the diaphragm to move cephalad into the thoracic cavity and subsequently depresses the chest wall allowing air to be rapidly expelled from the

lungs (Roussos, 1985). Surgical procedures can affect the integrity of these muscles and thereby affect the process of breathing.

The repercussions of abdominal surgery can be influenced by various factors such as the area of the surgery (upper versus lower abdominal surgery), the degree of difficulty (minor versus major abdominal surgery), the method of surgery (open abdominal surgery versus laparoscopic surgery) and the incision type (vertical versus transvers). These factors play a role as to the degree of post-operative dysfunction the surgery may produce. The incidence of respiratory muscle dysfunction is 2-5% with lower abdominal surgeries and 20-40% with upper abdominal surgeries. Although studies show that upper abdominal surgeries result in more post-operative pulmonary dysfunction, this result may not be limited to evidence regarding cholecystectomies, but may be similar for other surgeries such as liver resections (Siafakas, 2013). The difficulty of the surgery may also influence post-operative function where minor surgeries such as tubal ligation result in less intra-operative handling than major surgeries such as bowel resections (Joris, Kaba, Lamy, 1997). A major factor influencing post-operative pulmonary function is the surgical approach. Abdominal surgical procedures can be classified as either open (laparotomy via a vertical or horizontal incision) or closed (laparoscopic via the use of a scope). Abdominal surgery can be performed for procedures such as hernia repairs, gall bladder resection (cholecystectomy) and large bowel resection (hemicolectomy) (Manzano et al., 2008). Various incision types (vertical, transverse and combined) can be employed in order to gain access to the abdomen during open abdominal surgery. The transverse incision has been found to be advantages as its effects on post-operative function is less detrimental than with vertical incisions. However, the vertical incision through the rectus abdominus muscle allows for rapid entry into the peritoneal cavity for exploratory purposes as incision site can be easily extended when required for more complex cases (Grantcharov & Rosenberg, 2001). An incision through the rectus abdominus muscle, as with open abdominal surgery, is invasive and disturbs both the abdominal muscles and diaphragm. To avoid a larger abdominal incision, where possible, a laparoscopic approach is employed by means of smaller incisions. When compared to open abdominal surgery for cholestectomy, the laparoscopic approach resulted in less detriment to pulmonary function post-operatively (Hasuki, Meši, Dizdarevi, Keser, Hadiselimovi, Bazardanovi, 2002). This finding is supported by several other authors (Osman, Serpil, Umit, Ebru, Bulent, Mete, Omer, 2009; Joris, Kaba & Lamy, 1997; Coelho, de Araujo, Marchesini, Coelho, de Araujo Coelho, 1993, Hasuki et al., 2002; Joris, Kaba & Lamy, 1997). Therefore, laparoscopic surgeries have since become a more popular approach.

The disruption to the rectus abdominus muscle, adversely affects the patient's ability to produce force expiratory manoeuvres as the rectus abdominus muscle forms a part of the muscles that assist in expiration (Roussos, 1985). Disruption to the diaphragm negatively affects the patient's ability to

expand the chest and inspire (Siafakas, Mitrouska, Bouros, Georgopoulos, 1999; Frazee, Roberts, Okeson, Symmonds, Snyder, Hendricks, Smith, 1991; Chuter et al., 1990).

Open abdominal surgery is associated with a large incision site, increased intra-abdominal handling during surgery, and may lead to increased post-operative pain (Joris, Kaba & Lamy, 1997). Pain, if not managed adequately post-operatively, can further affect the patient's willingness to breathe deeply, cough effectively, and mobilize post-operatively (Tzani, Chetta & Olivieri, 2011; Richardson & Sabanathan, 1997). The type of incision employed is therefore an important factor influencing post-operative lung function, as poor lung function may lead to the development of post-operative pulmonary complications (PPCs).

### **Post-operative pulmonary complications (PPCs)**

The inability to cough and clear secretions adequately may lead to retention of secretions, which subsequently places the patient at higher risk of developing post-operative pulmonary complications (PPCs) (Kacmarek, Stoller & Heuer, 2013, Egans Fundamentals of Respiratory Care, p.904). O'Donohue (1992) characterized PPCs as "any pulmonary abnormality occurring in the post-operative period that produces identifiable disease or dysfunction that is significant and adversely affects the clinical course" (O'Donohue, 1992). The term PPC is problematic as it includes a variety of complications such as pneumonia, respiratory failure, bronchospasm, atelectasis, and exacerbation of underlying chronic lung diseases (Smetana, 1999). As this umbrella-term encompasses a host of dysfunctions and not clearly defined in literature, PPCs are predominantly described in terms of the development of pneumonia and atelectasis (Pasquina, Tramèr, Granier & Walder, 2006; Grantcharov & Rosenberg, 2001; Brooks-Brunn, 1995). In addition to this poor definition, the criterion for the diagnosis of PPCs is not standardized leading to the varying criteria used in literature (Conde & Lawrence, 2008; Mackay, Ellis & Johnston, 2005; Smetana, 1999; Lawrence, Dhanda, Hilsenbeck, Page, 1996). Current literature tends to report different signs and symptoms that define the presence of PPCs, therefore making a true classification of a PPC, by means of specific criteria, difficult. The table below summarises examples of conflicting criteria for the classification of PPCs (Table 1).

**Table 1: Summary of conflicting criteria for the diagnosis of PPCs**

Summary of conflicting criteria for the diagnosis of PPCs		
(Conde & Lawrence, 2008)	(Browning, Denehy & Scholes, 2007)	(Brooks-Brunn, 1995 and Hall, 1996 as modified by Mackay, Ellis & Johnston, 2005 )
PPC was associated with a combination of the following:	PPC was confirmed if 4 or more of the following signs and symptoms were present:	PPC are confirmed if 3 or more of the following respiratory signs occurred within the same day, in the first 14 days after surgery:
<ul style="list-style-type: none"> <li>€ Cough</li> <li>€ Phlegm</li> <li>€ Shortness of breath</li> <li>€ Chest pain</li> <li>€ Temperature &gt;38 °C</li> <li>€ Pulse rate &gt; 100 beats per minute</li> </ul>	<ul style="list-style-type: none"> <li>▪ Chest radiograph report of collapse/consolidation</li> <li>▪ Raised temperature &gt;38 °C on two or more consecutive days</li> <li>▪ SpO<sub>2</sub> &lt;90% on room air on two consecutive days</li> <li>▪ Production of yellow or green sputum which is different to pre-operative assessment</li> <li>▪ An otherwise unexplained white cell count &lt; 11X10<sup>9</sup>/L or prescription of an antibiotic specific for respiratory infection</li> <li>▪ Physician diagnosis of chest infection</li> <li>▪ Presence of infection on sputum culture report</li> <li>• Abnormal breath sounds on auscultation that differs from pre-operative assessment</li> </ul>	<ul style="list-style-type: none"> <li>o Auscultation changes (decreased breath sounds, crackles, wheezes, bronchial breathing) that were additional to those found prior to surgery</li> <li>o Temperature &gt;38 °C</li> <li>o Chest X-ray changes consistent with collapse, consolidation, or atelectasis</li> <li>o Increase in amount and/or changed colour of sputum produced, compared to what the patient reports is usual for them</li> </ul>

PPCs are often reported in terms of atelectasis and pneumonia and are often reported together. This is as patients who exhibit clinical signs of increased temperature are often started on antibiotics (Hall, Tarala, Hall & Mander, 1991). Atelectasis can be classified as either resorption atelectasis or passive atelectasis. Resorption atelectasis occurs when retained secretions result in mucus plugging, causing areas of the lung to collapse. Passive atelectasis is caused by the patient's inability to take deep breaths and persistently breathing at small tidal volumes and is further aggravated by poor mobility, as is commonly exhibited in patients following open abdominal surgery (Kacmarek, Stoller & Heuer, 2013, Egans Fundamentals of Respiratory Care, p.904). Retained secretions may also increase the patient's risk of developing post-operative pneumonia. Pneumonia that develops in hospitalized patients is commonly referred to as hospital-acquired pneumonia. Hospital-acquired pneumonia is defined as a lower respiratory tract infection that occurs in patients more than 48 hours after hospitalization and is caused typically by the spread of organisms such as *Staphylococcus aureus* and Enteric gram-negative bacilli between patients or equipment (Kacmarek, Stoller & Heuer, 2013, Egans Fundamentals of Respiratory Care, p.484-486).

Open abdominal surgery, as discussed previously, is an invasive procedure that often results in reductions in pulmonary function, post-operative pain, negatively influences post-operative mobility, and thus places the patient at risk of developing PPCs (Hasuki et al., 2002; Richardson & Sabanathan, 1997). Hall et al. (1991) suggested that PPCs occur in 19 to 76 percent of patients undergoing abdominal surgery (Hall et al., 1991). Fagevik Olsen et al. (1997) reported that PPCs occurred in 4.5-8 percent of patients undergoing upper abdominal surgery (Schmidt, 1977; Stiller and Munday, 1992; Thorén, 1954, Olsén, Hahn, Nordgren, Lönnroth, Lundholm, 1991). Other factors that further impact on lung volumes and the risk of the development of PPCs are the elderly, obese, smokers, and in patients with poor general pre-operative health (Smetana, 1999; Hall et al., 1991). PPCs have been found to be the main contributors to increased hospital stay and health costs (Tzani, Chetta & Olivieri, 2011; Brooks-Brunn, 1995; Hall et al., 1991). Therefore, adequate post-operative pain relief, techniques to improve pulmonary function and early mobilization are essential in the prevention of PPCs.

### **Cardio-respiratory physiotherapy post abdominal surgery**

Physiotherapy is suggested to play a valuable role in the prevention and treatment of PPCs post-abdominal surgery (Richardson & Sabanathan, 1997). Post-operative lung expansion techniques used by physiotherapists are reported to lower the risk of atelectasis by increasing lung volumes (Smetana, 1999). Manzano et al. (2008) reported improvements in oxygen saturation when comparing a chest physiotherapy regime to a control group of no intervention in the abdominal surgical population



(Manzano et al., 2008). Mackay, Ellis & Johnston (2005) investigated the use of physiotherapy in high-risk patients following open abdominal surgery. A total of 58 patients met the criteria, of which the results of 56 patients were included. This randomized control trial allocated patients into a group receiving early mobilization only and another group consisting of early mobilization, deep breathing exercises, and coughing. They found that there was no significance in outcomes between the two groups. The suggestion was that the addition of deep breathing exercises and coughing exercises to a programme, including early mobilization, did not significantly reduce post-operative pulmonary complications (Mackay, Ellis & Johnston, 2005).

However, in an earlier comparative study investigating breathing exercises such as the use of incentive spirometry (IS), intermittent positive pressure breathing (IPPB), and deep breathing exercises (DBE) results showed that DBE and IS respectively were more effective than no physiotherapy after abdominal surgery (Thomas & McIntosh, 1994). More than a decade later uncertainty still exists about the value of routine physiotherapy using these modalities (Pasquina, Tramèr, Granier, Walder, 2006). More recently, Hanekom et al. (2012) devised a treatment algorithm for the post-operative physiotherapy management of patients following upper abdominal surgery, which includes upright positioning, early mobilization, coughing with wound support, deep breathing exercises, and the use of Positive Expiratory Pressure (PEP) devices such as the Blow Bottle or PEP mask (Hanekom, Brooks, Denehy, Fagevik-Olsén, Hardcastle, Manie, Louw, 2012).

### **Positive Expiratory Pressure (PEP) therapy**

Positive Expiratory Pressure (PEP) therapy involves the application of positive pressure during the expiratory phase in the spontaneously breathing patient. It is aimed at airway clearance and improving tidal volume and functional residual capacity and can be applied in the treatment of both surgical and non-surgical patients with respiratory complications (Clini, 2009; Johnston, James & Mackney, 2013; Orman & Westerdahl, 2010; Elkins, Jones & Van der Schans, 2006; Darbee, Ohtake, Grant, Cerny, 2004; Tang, Taylor & Blackstock, 2010). The suggestion is that PEP therapy improves lung volume as the transpulmonary gradient increases by increasing the alveolar pressure. This assists in the prevention and treatment of atelectasis (Kacmarek, Stoller & Heuer, 2013, Egans Fundamentals of Respiratory Care, p.905). Furthermore, the positive pressure during expiration keeps the small airways open by improving collateral ventilation, and thereby assists in secretion clearance (Mestriner, Fernandes, Steffen, Donadio, 2009). Positive Expiratory pressure can be achieved, using no equipment, by means of pursed-lip breathing (Johansson et al., 2013). PEP therapy can be also be applied using devices manually constructed or devices that are commercially available. PEP devices can be classified as either flow or pressure generated devices where the PEP is either produced by passing the exhaled air through a fixed orifice whereby the pressure generated increases with the expiratory flow, or where the pressure remains constant regardless of the flow of exhaled air (Mestriner et al, 2009).

The “Blow Bottle” is one of the earliest forms of a manually constructed PEP device. It is the simplest form of a threshold-resistor PEP device (whereby the pressure remains constant regardless of flow). It consists of a bottle filled with water and a dwelling tube through which the patient is asked to blow (Ricksten, Bengtsson, Soderberg, Thorden, Kvist, Ricksten, 1986). It is also referred to in literature and in practice as the “Positive End-Expiratory Pressure (PEEP) Bottle”, “PEP Bottle” or “Bubble PEP” (Mestriner, Fernandes, Steffen & Donadio, 2009; Sehlin, Ohberg, Johansson, Winso, 2007). The Blow Bottle is typically used intermittently and is dependent on the patient’s ability to perform the expiratory manoeuvre (Orman & Westerdahl, 2010). It is commonly constructed using available hospital materials such as sterile water or saline solution bottles, together with suction tubing or urinary catheter tubing. The expiratory pressure produced by the manually constructed Blow Bottle is difficult to measure in practice, as it cannot be fitted with a manometer. However, investigations suggest that a water column of 10cm generates a pressure of 10cmH<sub>2</sub>O within the lungs, implying that the level of water is proportional to the positive pressure exerted within the lungs (Mestriner et al., 2009; Sehlin et al., 2007). A laboratory study by Mestriner et al. (2009) described the optimum design parameters for a manually constructed Blow Bottle of which a water column of 10cm with a tube inner diameter of  $\geq 8$ mm and an air orifice of  $\geq 8$ mm. These parameters allow for the production of a threshold-resistor PEP device, where pressure is provided purely by the water column. It was shown that when the inner diameter of the airway tube size and the length of the tube is reduced, it resulted in a much higher PEP than indicated by the water level alone. Although this was a laboratory study, findings were comparable with those concluded in studies investigating Blow Bottle design parameters in human subjects (Sehlin et al., 2007; Christensen, Jensen, Schonemann, Petersen, 1995). Literature also mentions the adverse effects of the Blow Bottle, which includes pathogens developing in the device itself, increased work of breathing during the use of the Blow Bottle, and general safety concerns such as risk of aspiration. The device itself may be a possible site for pathogens, as the water in the bottle may not be changed regularly (Johnston, James & Mackney, 2013). An incorrectly constructed Blow Bottle device may result in a larger positive pressure being produced and therefore may lead to increased work of breathing and respiratory muscle fatigue during the use of the Blow Bottle (Mestriner et al., 2009). The Blow Bottle may become an electrical safety hazard, should it leak or fall over or placed near electrical equipment. As the Blow Bottle contains water, this may be an aspiration risk if patients are insufficiently cognitively aware and inadvertently drink the water from the container or inhale instead of exhaling during the treatment (Johnston, James & Mackney, 2013). In the 1970’s, the PEP mask was introduced, exchanging the water column and tube for a variable resistor, mask, and manometer (Sehlin et al., 2007; Fagevik Olsén, Hahn, Nordgren, Lönroth & Lundholm, 1997). Commercial PEP devices have since grown to include devices that create vibrations during exhalation, and can be classed under the umbrella term Oscillating PEP or OPEP. Such devices include the Acapella, Flutter, and Quake (Clini, 2009; Myers, 2007). These PEP devices generally showed generating a mean expiratory pressure range of 5-20 cmH<sub>2</sub>O (Mestriner et al., 2009;

Darbee, Ohtake, Grant & Cerny, 2004). Specific prescriptions, that is, the number of repetitions; level of the water or amount of PEP employed for the use of the Blow Bottle and PEP devices vary in literature. Some asked patients to blow for two sets of ten per hour (Campbell, Ferguson & McKinlay, 1986); blow for 10 minutes every fourth hour (Heisterberg, Johansen, Larsen, Holm, Andersen, 1979); five breaths per hour (Hanekom et al., 2012), blow for five minutes per hour (De Pietri, Montalti & Begliomini, 2014). Fagevik Olsén (2015) suggested that varied prescription and dosage of PEP devices may be required to address different pathologies such as pneumonia versus atelectasis (Olsén, Lannefors & Westerdahl, 2015).

Although the Blow Bottle has evolved, in clinical practise in South Africa, the Blow Bottle is a common adjunct to physiotherapy, perhaps as it is easily constructed using inexpensive and accessible materials found in most hospitals (Johnston, James & Mackney, 2013; Johansson et al., 2013; Clini, 2009).

### **PEP Therapy and Abdominal Surgery: The use of the Blow Bottle**

A recent survey of public hospitals in New South Wales, Australia, reported that manually constructed PEP devices such as the Blow Bottle were more commonly used than those commercially available. PEP was used primarily in respiratory conditions as a means of secretion clearance, treatment, and prevention of alveolar collapse, prevention of complications, and reduction of shortness of breath (Johnston, James & Mackney, 2013). The recommended dosage for the use of the Blow Bottle post abdominal surgery varies from 3 to 30 blows every hour (Johnston, James & Mackney, 2013; Orman & Westerdahl, 2010). Few respondents also reported that they used the PEP bottle as a “visual reminder” for patients to do their exercises (Johnston, James & Mackney, 2013). A recent Swedish study reported similar results where survey results showed that the Blow Bottle was the most common PEP therapy device used in the post-operative management of abdominal surgery (Johansson et al., 2013). Orman and Westerdahl (2010) did a systematic review investigating the use of PEP therapy after thoracic and abdominal surgery.

Six articles were included in this review and only one showed any positive effects of PEP when compared to other physiotherapy breathing techniques. Of the six articles included in the review, only four investigated abdominal surgery and only two of the four evaluated the use of the Blow Bottle, which is Heisterberg et al. (1979) and Campbell et al. (1986). In the Heisterberg article, the Blow Bottle technique was compared to a bi-daily physiotherapy regime including breathing exercises and postural drainage. No significant difference was found between the groups regarding scoring of atelectasis. The Campbell study compared a physiotherapy regime to a physiotherapy regime with the additional use of the Blow Bottle. Results showed that there was no significant improvement regarding post-operative pulmonary complications. When compared to conventional physiotherapy, the additional use of PEP added no significant benefits. Of the six studies included in this systematic review, only one was performed out of Scandinavia. Both studies, which included the use of the Blow

Bottle, were published more than 20 years ago, highlighting the lack of recent evidence for the use of the Blow Bottle in this field (Orman & Westerdahl, 2010).

## **1.2 Rationale for the study**

Post-operative cardio-respiratory physiotherapy for patients undergoing abdominal surgery has been found to be beneficial in improving lung function and the prevention and treatment of PPCs (Manzano et al., 2008; Richardson & Sabanathan, 1997). The Blow Bottle PEP device is commonly used in the clinical setting perhaps as it is low cost and more easily accessible, as physiotherapists can construct it themselves (Johnston, James & Mackney, 2013; Johansson et al., 2013; Clini, 2009). However, evidence to support the use of Blow Bottles in the post-operative management of abdominal surgery is minimal and outdated, with few studies reporting significant positive effects especially when compared to conventional physiotherapy techniques (Orman & Westerdahl, 2010; Pasquina et al., 2006; Richardson & Sabanathan, 1997; Hall et al., 1996). Therefore, this study serves to investigate the additional use of the Blow Bottle to conventional cardio-respiratory physiotherapy to improve patient outcomes, namely, lung function and the development of PPCs.

## **1.3 Research Question**

How does the addition of the Blow Bottle to conventional post-operative cardio-respiratory physiotherapy (a regime of early mobilization and deep breathing exercises) affect post-operative lung function as measured by FEV<sub>1</sub> and FVC and the development of PPCs?

## **1.4 Aim of the study**

To investigate the effects of the Blow Bottle as an addition to conventional post-operative cardio-respiratory physiotherapy on post-operative outcomes and to determine whether the addition of the Blow Bottle is more beneficial.

## **1.5 Objectives of the study**

To determine how the addition of the Blow Bottle to conventional post-operative cardio-respiratory physiotherapy affects:

1. Lung-function (as measured by means of spirometry using the Spirolab™ portable spirometer), forced expiratory volume in one second (FEV<sub>1</sub>), and forced vital capacity (FVC).
2. The development of PPCs: with PPC defined as 3 or more of the following respiratory signs occurring within the same day, in the first 14 days after surgery (Mackay, Ellis & Johnston, 2005):
  - Changes in auscultation (decreased breathe sounds, crackles, wheezes, bronchial breathing) that were additional to those found pre-operatively
  - Temperature over 38 degrees Celsius

- Chest X-ray changes consistent with collapse, consolidation, or atelectasis
- Increase in amount and/or change in colour of sputum produced, compared to what the patient reports pre-operatively

### **1.6 Null Hypothesis**

There is no difference in effects on post-operative outcomes between conventional post-operative cardio-respiratory physiotherapy and conventional cardio-respiratory physiotherapy with the additional use of the Blow Bottle.

## **1.7 Abbreviations**

In order of appearance:

PPCs- Post-operative Pulmonary Complications

PEP- Positive Expiratory Pressure

FEV<sub>1</sub>- Forced Expiratory Volume in 1 second

FVC- Forced Vital Capacity

A-APODS-Adapted Abdominal Surgery Physiotherapy Outcomes Data Sheet

NRF- National Research Fund

CPRG- Cardio Pulmonary Rehabilitation Group

PEEP- Positive End Expiratory Pressure

GIT- Gastro Intestinal Tract

HPB- Hepato Biliary

SATS- South African Thoracic Society

ATS- American Thoracic Society

ERS- European Respiratory Society

APODS- Abdominal Surgery Physiotherapy Outcomes Data Sheet

CT scan- Computerized Tomography scan

## **1.8 Glossary**

All glossary items retrieved using Medline Plus (U.S National Library of Medicine) as obtained from <https://www.nlm.nih.gov/medlineplus/mplusdictionary.html> in August 2015.

Laparotomy: Surgical section of the abdominal wall

Hemicolectomy: Surgical excision of part of the colon

Cholecystectomy: Surgical excision of the gall bladder

## **CHAPTER 2: METHODOLOGY**

### **2.1 Introduction**

This chapter will describe in detail the methodology used to answer the research question. This includes a description of the research setting, study design, and participants. Instrumentation, procedures, ethical and statistical considerations used to implement and analyse the above will be elaborated on below.

### **2.2 Research Setting**

The primary study was conducted at two private hospitals and one public tertiary hospital within Cape Town in the Western Province. The two chosen private hospitals form part of one of the largest private hospital networks in South Africa (Life Healthcare Website as accessed on 1 March 2015). The study was carried out in their Gastro-intestinal (GIT) Units. The public hospital included in this study is one of the leading tertiary academic hospitals in South Africa (Western Cape Government Website as accessed on 1 March 2015). The study was conducted specifically within the hospital's Colorectal and Hepatobiliary (HPB) units. This public tertiary institution services the Southern Suburbs, Cape Metropolis, and surrounds. Private hospitals, unlike the state hospitals, are not restricted to providing their specialized services according to municipal boundaries, with the result that patients may be referred from any geographic area, even from neighbouring states or countries.

### **2.3 Research Design**

The researcher used a single blinded randomized control trial with repeated measures design.

#### **2.4.1 Sample Size**

The ideal sample size was calculated using STATISTICA version 12.5 ([www.statsoft.com](http://www.statsoft.com)), which calculated that a total number of 74 participants would provide a 90% chance of detecting a large effect size for this trial. It was calculated that 37 participants per group were needed if the mean predicted FEV<sub>1</sub> (L/s) of the control group was at estimated at 69.6 % FEV<sub>1</sub> and the mean predicted FEV<sub>1</sub> (L/s) of the experimental group was estimated at 79.9 % FEV<sub>1</sub> with a standard deviation of 13.3 and  $p < 0.05$ .



## **2.5 Participants**

### **2.5.1 Inclusion and exclusion criteria**

#### **Inclusion criteria**

Patients were included if they were 18 years of age and older, admitted from home and scheduled to undergo elective open abdominal surgery via midline incision. Patients were scheduled for surgery and admitted through the Hepatobiliary (HPB), or Colorectal surgical units within the public sector, and Gastro-intestinal (GIT) units within the private sector. The decision to include these units is because these units typically perform elective open laparotomies via midline incisions. In addition, sampling participants exclusively from these units was to ensure that participants with similar conditions and surgical requirements were present within the sample group. For purposes of consent, participants over the age of 18 years were included. All patients were eligible for inclusion if they were orientated to time/person and place and able to communicate in English. This was to ensure that patients were able to actively participate during the pre-operative session and the post-operative physiotherapy treatment.

#### **Exclusion criteria**

Patients already hospitalized and awaiting open abdominal surgery were excluded from the study, as these patients may have already been referred for in-patient physiotherapy, which might influence the results of the study. Patients fulfilling the inclusion criteria but remained ventilated for longer than 24 hours directly after elective surgery were excluded, as patients are not routinely ventilated post-operatively and ventilation and intubation would deem the patient unable to use the Blow Bottle treatment.

### **2.5.2. Sampling Method**

The researcher used a sample of convenience, in that every patient who met the criteria was approached for recruitment.

### **2.5.3. Recruitment of participants**

Ethical approval and institutional approval was obtained from the selected trial sites (see 2.12). The institution and surgical teams of the HPB, Colorectal and GIT units relevant to the institution granted access to the theatre lists. Names of the patients eligible for the study were extracted from the theatre list. Patients undergoing surgery and admitted through these units were routinely admitted the day before surgery. Patients on the theatre list were then approached pre-operatively, given an information letter, informed about the trial, and asked whether they would like to participate. Further information and informed consent was then gained from those patients willing to participate. Thereafter, pre-

operative details were gathered to establish a baseline. Patients were informed that if they were not willing to participate in the trial, their surgical procedures, and post-operative management would continue as usual (see page 2.12). The primary researcher carried out this process.

#### **2.5.4. Randomization**

Participants were randomized into two groups:

1. The control group (CG) receiving conventional post-operative cardio-respiratory physiotherapy
2. The intervention group (IG) receiving conventional post-operative cardio-respiratory physiotherapy with the additional use of the Blow Bottle

Participants were allocated to the treatment or control group by means of simple randomization, using a computer generated random number process to allocate the participants to either the control or treatment group ([www.randomization.com](http://www.randomization.com)) (see 2.8.2).

### **2.6. Description of Conventional Group and Intervention Group Regimes**

#### **2.6.1. Conventional Cardio-respiratory Physiotherapy**

Both groups (CG and IG) received conventional post-operative cardio-physiotherapy. Conventional cardio-respiratory physiotherapy included breathing exercises inclusive of non-PEP breathing devices, manual chest physiotherapy techniques inclusive of a combination of vibration, percussions, coughing, and exercises inclusive of general exercise and mobilization. The conventional cardio-respiratory physiotherapy treatment was conducted a minimum of once daily from Day 1 post-surgery, and continued till the participant was discharged from hospital or deemed ready to be discharged from physiotherapy by the treating physiotherapy team. Readiness for discharge from physiotherapy was based on the participants' ability to mobilize adequately and their chests deemed clear (dependent on their ability to clear secretions if any, and no signs of respiratory complications). Conventional treatment was carried out as the physiotherapy team deemed appropriate and as per the routine practises of the physiotherapy team. The physiotherapist documented the treatment given to the participants on the Adapted Abdominal Surgery Physiotherapy Outcomes Data Sheet (A-APODS) (see Appendix A). Evaluation by the researcher continued until the participant was discharged from physiotherapy.

#### **2.6.2. Intervention Group Therapy**

Participants allocated to the treatment group received conventional cardio-respiratory physiotherapy as described above with the additional use of the Blow Bottle during the physiotherapy session. The primary researcher constructed the Blow Bottle and filled it with 10cm of water (2.7.1). The physiotherapist instructed the participants to use the Blow Bottle by taking a deep inhalation and exhaling slowly by blowing bubbles via the tube in the bottle. This was repeated a minimum of 10

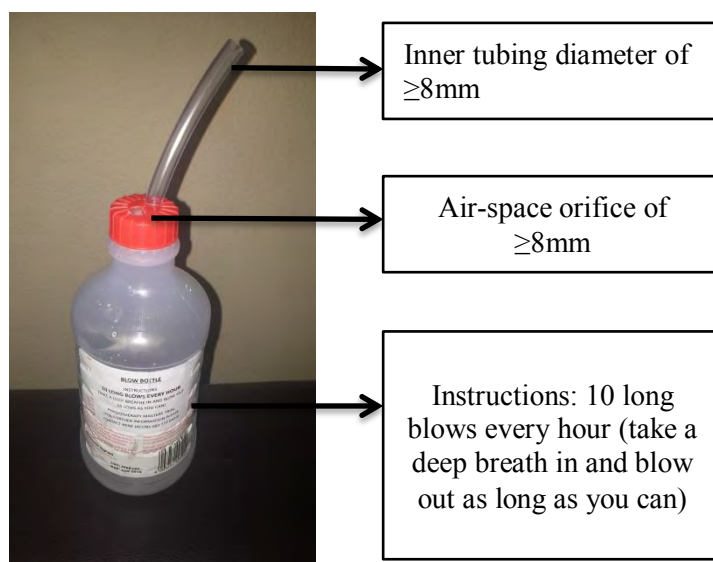
times during the session. For the purposes of this study, atleast 10 breathes every hour was chosen as articles investigating the use of PEP devices varied on the specific dosage of the PEP device implemented (Campbell, Ferguson & McKinlay, 1986; Heisterberg et al., 1979; Hanekom et al., 2012; De Pietri, Montalti & Begliomini, 2014). Therefore, hourly treatment of 10 breathes were used as this was observed as common practice. The physiotherapist recorded the resistance and repetitions executed during the treatment on the A-APODS (see Appendix A). Participants were encouraged to self-administer the device as taught, every waking hour.

## 2.7 Measurement instruments

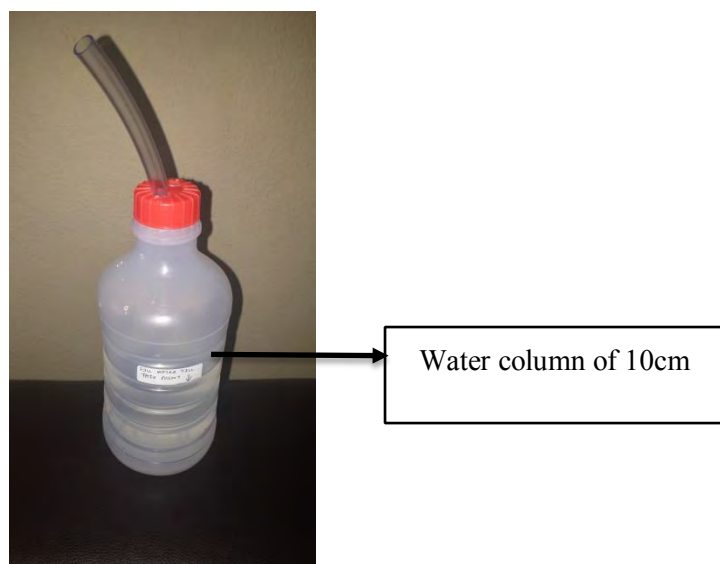
### 2.7.1. The Blow Bottle

The primary researcher constructed the Blow Bottle and gave them to the physiotherapy team of the hospital to distribute to participants within the IG. The optimum design for a therapist constructed Blow Bottle was shown to comprise of an inner tubing diameter of  $\geq 8\text{mm}$ , an air-space orifice of  $\geq 8\text{mm}$ , and a water column of 10cm. This generated a pressure of 10cmH<sub>2</sub>O (Mestriner et al., 2009). These specifications were therefore used to construct the Blow Bottles for this trial (see Illustration 1 & 2).

Illustration 1: Blow Bottle (front view)



**Illustration 2: Blow Bottle (rear view)**



### **2.7.2. Blow Bottle Logbook**

The primary researcher developed a logbook as a means to record the compliance with the self-administration of the Blow Bottle. This logbook contained an hourly record of the use of the Blow Bottle by the participant and where after a member of the nursing staff who witnessed the participant using the Blow Bottle signed it off (see Appendix C).

### **2.7.3. Lung Function Testing**

Lung function was chosen as an outcome measure to identify and quantify the participants' pulmonary mechanics. Lung function testing via spirometry proved to be an effective tool to evaluate the effectiveness of therapeutic interventions (Kacmarek, Stoller & Heuer, 2013, Egans Fundamentals of Respiratory Care, p.400). FEV<sub>1</sub> and FVC were therefore chosen as the primary lung function parameters. Several studies investigating the abdominal surgical populations use these variables as an outcomes measure and have shown that open abdominal surgeries are associated with respiratory compromise and reduced lung function post-operatively as evident in reduced measurements of FEV<sub>1</sub> and FVC (von Ungern-Sternberg, Regli, Schneider, Kunz & Reber, 2004; Hasuki et al., 2002; Smetana, 1999; Joris, Kaba & Lamy, 1997). The measurement of other spirometry variables such as FRC (Functional Respiratory Capacity) and TLC (Total Lung Capacity), although they provide a more accurate measurement of lung function, they are very difficult to measure at the patient's

bedside, hence re-enforcing the decision to include FEV<sub>1</sub> and FVC as the outcomes measures. Spirometry variables FEV<sub>1</sub> (Forced Expiratory Volume in one second) and FVC (Forced Vital Capacity) were recorded. These are typically measured spirometry variables and considered the most important aspects of spirometry. FVC pertains to the maximal volume of air the subject is able to exhale with maximum effort from an inspiration of maximum capacity. FEV<sub>1</sub> pertains to the maximal volume of air the subject is able to exhale in the first second of a forced expiration from an inspiration of maximum capacity (Miller, Hankinson, Brusasco, Burgos, Casaburi, Coates, Crapo, Enright, 2005). The normal values for FVC and FEV<sub>1</sub> are expressed as 5L for FVC and 4L for FEV<sub>1</sub> as published in Egan's Fundamentals of Respiratory Care, ninth edition (Kacmarek, Stoller & Heuer, 2013; Miller et al., 2005). The Spirolab™ colour LCD MIR portable spirometer was used in this study and calculates the predicted lung function values for FEV<sub>1</sub> and FVC using the ERS (European Respiratory Society) predicted values relating to the patients age, gender, height, weight and ethnicity as entered by the user. For this study, the option to calculate predicted values without ethnicity was selected. This was as the South African population and anticipated sample population is diverse, and literature describing standardized predicted value norms for the African population is minimal and absent for the South African population (Koegelenberg, Swart & Irusen, 2013; Quanjer, Stanojevic, Cole, Baur, Hall, Culver, Enright, Hankinson, 2012). Therefore, to establish changes in lung function the patients' pre-operative baseline and predicted spirometric values we measured against those obtained post-operatively.

The manufacturer calibrated the Spirolab™ 3-colour LCD MIR portable spirometer prior to the study and on two occasions during the course of the study. The manufacturer also checked the software and hardware of the device on these occasions. Lung function testing was conducted pre-operatively during the initial contact session, and daily post-operatively commencing on Day 1 post-surgery, by the primary researcher only, who was blinded to group allocation. Standard procedures for the use of spirometry as described by Koegelenberg et al 2013 were adhered. The guidelines by Koegelenberg et al. (2013) are representative of the views of the South African Thoracic Society (SATS) and incorporate the findings of the American Thoracic Society (ATS) and the European Respiratory Society (ERS) (Miller et al., 2005). All spirometry testing were performed with the participant in a seated position or an upright position in bed. During the pre-operative session, the spirometry testing procedure was explained thoroughly and participants' were shown how to execute the lung function manoeuvres, instructed, and demonstrated by the primary researcher. Participants were instructed as follows: participants were asked to inhale completely and rapidly, place the mouthpiece in the mouth and seal their lips around the mouthpiece, then exhale maximally until no more air could be expelled. On each occasion when spirometry was tested, the participants were again instructed on how to execute the manoeuvre. At each measurement time, the participants were asked to perform the manoeuvre for the testing for FVC and FEV<sub>1</sub>. The Spirolab™ 3-colour LCD MIR portable spirometer was able to test and display the accuracy and repeatability of the test. A minimum of three attempts

and a maximum of eight attempts were performed and the average reading of the three best attempts was recorded.

#### **2.7.4. The Adapted Abdominal Surgery Physiotherapy Outcomes Data Sheet (A-APODS)**

Mackay et al. (2005) in their study investigating physiotherapy in the abdominal surgical population used a data sheet to record various outcome measures during their study (Mackay, Ellis & Johnston, 2005). This data sheet was referred to as the “Abdominal Surgery Physiotherapy Outcomes Data Sheet” or “APODS” (see Appendix B). The purpose of the APODS was to record data pertaining to the following categories:

- Pre-operative data: including demographic information, co-morbidities, and pre-operative risk factors.
- Operative data: including the duration of anaesthesia and intra-operative details.
- Post-operative data: This included the development of post-operative complications and the type of antibiotics and analgesic drugs used. Physiological outcomes such as the development of PPCs and mobility outcomes in terms of the restoration of mobility were also recorded.
- Staffing details: Employment and experience of the treating physiotherapists.

Mackay et al. (2002) first developed the APODS instrument and tested the reliability and validity of the instrument. The APODS demonstrated good content and predictive validity and high intra-rater and inter-rater reliability. The APODS obtained a Kappa co-efficient range from  $k=0.64-1.00$  indicating substantial intra-rater reliability. The inter-rater reliability Kappa statistic ranged from  $k=0.69-1.00$  indicating substantial agreement in the majority of the data categories. In terms of predictive validity, the APODS showed a 2% chance of indicating a false positive in diagnosing the development of a PPC, and 0% chance of finding a false negative result. The information regarding the reliability testing and development of the APODS was gathered from the two articles Mackay (2003) and Mackay et al. (2005), as well as from personal communication with the author, and unpublished documentation acquired from her (Mackay MR, 2003).

#### **Development of the A-APODS**

The APODS was quite long (three pages long) and would have required extensive time for busy clinicians in a resource constrained environment like South Africa to complete, the APODS was therefore condensed. The APODS was condensed into a 2-page document that comprised of the most important categories relevant to the study. This document was then referred to as the Adapted Abdominal Surgery Physiotherapy Outcomes Data Sheet or A-APODS (see Appendix A). All the key categories in the APODS were kept, with the exception of the intra-operative and staffing details, as some details within these categories recorded in the APODS were observed to not be typically recorded in South African hospital institutions (both private and public). For example, the APODS documented details regarding the intraperitoneal sepsis during the time of the surgery and the

American Society of Anaesthesiologists' classification of physical status (ASA) score. These were therefore omitted. In addition, a category for the recording of the physiotherapy treatment given and the use of the Blow Bottle was added.

### **Content Validity of the A-APODS**

The first draft of the A-APODS document was circulated amongst three physiotherapists with expertise in the field of cardio-respiratory physiotherapy. Each physiotherapist selected to review the A-APODS document were either in senior physiotherapy or lecturing positions and had a minimum of 20 years' experience in physiotherapy. The physiotherapists were requested to give written or verbal feedback as to the content of the data sheet, the readability of the document, and any additional information that they regarded necessary to remove or insert into this document. Their input indicated the need to change the document from a scoring system used in the APODS to a tick system, as it would be easier to complete in practise (see Appendix B). All agreed that the data recorded on the document, however detailed, was comparable to what may be recorded by a physiotherapist during usual physiotherapy practice.

A second draft of the A-APODS with the necessary amendments was then circulated amongst the physiotherapy teams at the selected sites for the randomized control trial, requesting feedback regarding the feasibility of completing the document on a daily basis. The physiotherapy teams suggested that the document be bound to allow for ease of transportation during treatment rounds. This suggestion was acknowledged and implemented. The reliability of the A-APODS was then evaluated during the Pilot study.

## **2.8 Research Procedures**

This section elaborates on the training of staff and research personnel, followed by the blinding and randomization procedures employed. The pilot study and findings will also be described. The primary aspect of this section is the data collection procedure and will be described in detail.

### **2.8.1. Training of staff and research personnel**

#### **Physiotherapists**

Prior to the commencement of the trial, the primary researcher met with the physiotherapy teams of the respective institutions. The procedures were then discussed and the role of the physiotherapists during the trial explained. The physiotherapists were all taught how to use the Blow Bottle and how to instruct participants to use the device. The randomization procedure and its implementation were also explained. The logbook, to measure compliance for use of the Blow Bottle was discussed and the physiotherapists asked to distribute it when the participants were given their Blow Bottle. The physiotherapists were also briefed on how to complete the A-APODS and notified that data needed to

be collected daily and only returned to the primary researcher once the participant had been discharged from physiotherapy.

### **Research personnel**

Research personnel were employed to assist with the blinding procedure. Since the primary researcher was blinded as to which group the participants were allocated to, they were briefed to remove all evidence of the participants' group allocation such as the Blow Bottle and logbook prior to the primary researcher coming to conduct the participants' spirometry readings. The research personnel also assisted in returning the Blow Bottle and logbook to the participant after the primary researcher had left the unit.

### **Nursing staff**

The nursing staff was informed about the trial and the procedures involved. They were introduced to the research team. The Blow Bottle, including its background, use and implementation was explained to the nursing staff. They were informed that the participants allocated to the Blow Bottle group need to use the Blow Bottle at least 10 times every hour. The nursing staff was also taught how to use the Blow Bottle, by blowing out into the tube as long as possible but not till all the air is expelled out of the lungs. They were informed that the physiotherapist would instruct the participant on how to use the Blow Bottle and implement the use of the device during the physiotherapy session. The nursing staff were requested to encourage participants and assist participants, if necessary, to use the Blow Bottle every hour. They were also asked to assist participants with the self-administration of the Blow Bottle device and ensure participants comply by using the logbook and signing it after use (see Appendix C).

### **2.8.2. Randomization Procedure**

As a first step, the primary researcher generated a list of successive numbers that would be assigned to consecutive participants. These numbers were then entered into the randomization website ([www.randomization.com](http://www.randomization.com)). This website allows for a computer generated randomization programme that assigned these successive numbers arbitrarily to either the CG or IG. The randomization process allows each printed document to contain a different randomized allocation, generating several versions of the allocation process. This was printed out on several sheets that were given to the physiotherapy teams of the various institutions. They then selected at random which sheet they would use for the trial. This process allowed the group allocation to be concealed from the primary researcher.



### **2.8.3. Blinding Procedure**

The researcher used a single blinded protocol. The computer generated randomization process was concealed to the primary researcher. The primary researcher only became aware of the participant's group allocation once the participant was discharged from physiotherapy and exited the trial. In addition, as the researcher conducted the lung function spirometry testing, research assistants were employed to ensure the blinding procedure was followed daily. They were set with the task of removing the Blow Bottle and logbook prior to the primary researcher coming to conduct the participants' spirometry readings and returning it once the primary researcher had left the unit. As outcomes were recorded on the A-APODS, this document was only returned to the primary researcher once the participant had been discharged from physiotherapy. This was to ensure that the primary research remained blinded during the data collection process.

### **2.8.4. Pilot Study**

The primary aims of the pilot study was to evaluate how the physiotherapists were able to implement the Blow Bottle intervention and record the data necessary to complete the A-APODS. The pilot study was conducted at a private hospital in the Southern Suburbs forming part of the sixth largest private hospital group in the world (Constantiaberg Medi-Clinic Website as accessed on 1 March 2015). The researcher chose this institution due to its convenience and accessibility to the primary researcher. Ethical approval was received for this study and verbal approvals from the hospital and nursing management as well as physiotherapy teams were received prior to the commencement of the pilot study. All patients admitted for any open abdominal surgery were eligible for the trial. All participants were included as per the inclusion and exclusion criteria (see 2.5.1). The pilot study therefore included a sample size of 13 participants. This pilot phase ran over a 3-month period from 01 November 2013 until 30 January 2014.

### **Pilot Study Findings**

The pilot study served to ascertain the efficacy of the data collection process, the intervention, as well as the reliability of the A-APODS. The physiotherapy team consisted of four physiotherapists. Using the A-APODS, the treating physiotherapists were able to extract the relevant data from the medical records. The physiotherapists reported that recording the use of the Blow Bottle and the physiotherapy treatment given was easy and not labour intensive. As the patients may be treated by a variety of physiotherapists during their duration of hospitalization, as no patient is treated exclusively by one physiotherapist, it was observed that most physiotherapists were able to record majority of the information. The physiotherapists were able to implement the use of the Blow Bottle into their physiotherapy regime with ease. The participants were able to use the Blow Bottle during the physiotherapy sessions and verbally reported that they used the Blow Bottle in between sessions without the assistance of the physiotherapy team. The A-APODS showed to reproduce results in

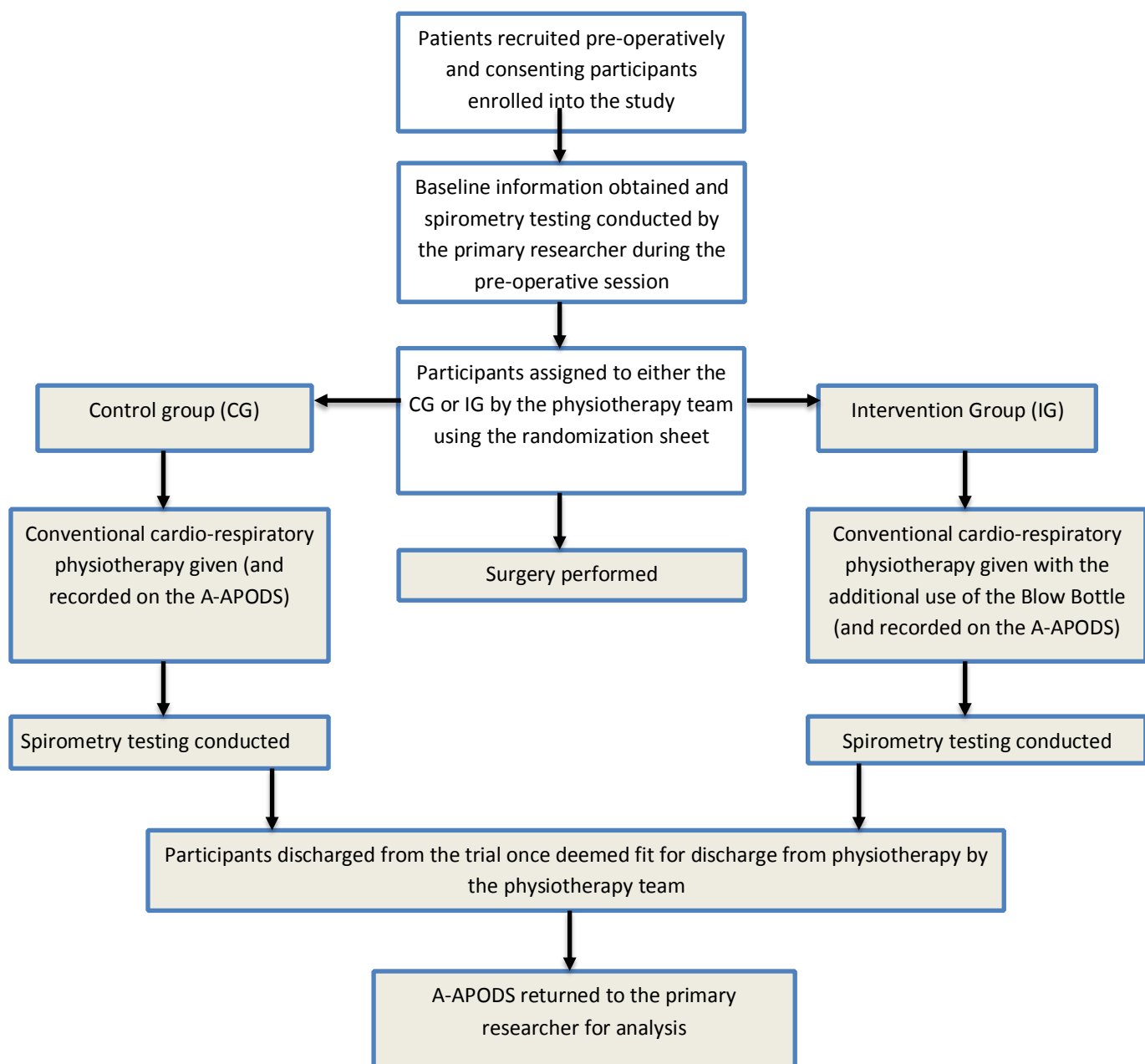
agreement between the treating physiotherapists. Very little missing data was observed and the physiotherapists reported that the data sheet was straightforward and easy to complete.

## **2.9 Collection Procedure**

Drawing from the pilot study and the procedures previously explained, the data collection procedure for the primary trial was developed. The data collection process will be explained in detail below, followed by a flow diagram representing the key elements of the data collection process. The data collection procedure was therefore as follows:

Patients were recruited the day before their scheduled surgery. Consenting participants were then enrolled into the study (see 2.12). During the pre-operative consultation, baseline information was recorded and the pre-operative spirometry measurements done by the primary researcher. This baseline information was then forwarded to the physiotherapy teams. Participants were then randomly allocated to either the CG or IG by means of a computer generated randomization process as previously described (see 2.8.2). Participants then underwent their scheduled surgery after which physiotherapy commenced on the first post-operative day. Physiotherapy as per the CG and IG intervention programmes then continued daily until the participants were deemed fit for discharge from physiotherapy, that is, they were assessed to be able to clear secretions effectively and were able to mobilize adequately.

All post-operative outcomes such as temperature, auscultation findings, imaging investigations (chest x-rays or CT scans), sputum, as well as the Blow Bottle and physiotherapy treatment were documented by the physiotherapy team per treatment session on the A-APODS (see Appendix A) . The primary researcher conducted spirometry measurements on a daily basis. The blinding procedure as described previously were adhered to during the study with research personnel ensuring that evidence of group allocation would be concealed to the primary researcher (see 2.8.3). The physiotherapy team kept the A-APODS data sheet, brought it to each physiotherapy session for completion, and returned it to the primary researcher for analysis after the participant exited the trial. The flow diagram below graphically describes the above section.



**Figure 1: Data Collection Procedure Flow Diagram**

## 2.10 Data Management

The physiotherapy teams kept all A-APODS documents securely in a locked cupboard in their offices. The A-APODS documents were then returned to the primary researcher after the participant had been discharged and were safely stored during the data analysis process.

## 2.11 Statistical Analysis

Data was analysed using STATISTICA version 12.5 ([www.statsoft.com](http://www.statsoft.com)). Data was analysed in relation to specific objectives. To assess the effects on lung function parameters, the effect of

randomized treatment (CG vs. IG) and time (Day of treatment) on FEV<sub>1</sub> and FVC of participants were analysed using repeated measures ANOVAs, followed by *post-hoc* Tukey tests. The development of PPCs is a composite outcome measure (that is, made up of several variables such as changes in auscultation, imaging, temperature, and sputum analysis). These categorical variables were analysed using a two-way Chi-squared test with Yates correction factor applied for low cell counts. A sub-analysis of the four individual categorical variables making up the composite outcome of PPC was similarly analysed using two-way Chi-squared tests. To do so, outcome measures were considered as binary events (yes/no) when differences from their pre-operative measures were noted; for example, on an individual level an auscultation was described as present (yes) when any post-operative measure of auscultations was noted as different from normal breath sounds observed pre-operatively. Assumptions for parametric statistical tests were investigated by means of P-plots (normality) and Levene's test (homogeneity of variance).

## **2.12 Ethical Considerations**

Ethical approval was received from the University of Cape Town through the Health Sciences Human Research Facility, HREF: 493/2013 (see Appendix D). Ethical approval was then renewed in 2014 (see Appendix E). Institutional approval was received from each institution involved in either the pilot or the primary trial. The private institutions used for the primary trial were constituents of the same network of hospitals. Written approval to conduct the primary trial within this network was received (see Appendix F). This approval letter was then presented to the hospital and nursing management teams of the respective institutions, who gave verbal approval to conduct the trial within their facilities. Approval from the public tertiary hospital was also received (see Appendix G). The researcher discussed the trial and expectations with the hospital management, nursing management, surgeons, and physiotherapy teams, and each gave verbal approval to conduct the study and agreed to assist where necessary.

This section will briefly describe various aspects for ethical consideration associated with the study including autonomy, beneficence, non-maleficence, confidentiality, justice, and the related risks and benefits. Informed consent will be elaborated on and described below.

### **Autonomy**

Patients were approached pre-operatively the day before surgery and the trial and all procedures discussed. Participants were given the opportunity to ask questions and clarify information and given time for participants to refuse treatment. Patients were informed that if they were not willing to participate in the trial, their surgical procedures, and post-operative management would continue as usual and not be affected in any way.

**Beneficence**

Each participant received the routine care of the specific institution, which was conventional cardio-respiratory physiotherapy. The treatment group had their physiotherapy treatment supplemented with the use of the Blow Bottle. Each participant received the same level of routine cardio-respiratory physiotherapy.

**Non-maleficence**

Each participant received routine conventional cardio-respiratory physiotherapy as per normal practices of each institution.

**Confidentiality**

All data was recorded with anonymity by assigning each participant to a coded reference number.

**Justice**

The IG received the Blow Bottle device. Literature mentions the benefits of the use of this device, but no clear evidence to its superiority over physiotherapy techniques alone were established, especially in this population. Both groups received conventional cardio-respiratory physiotherapy as it was part of routine hospital practise, and research made evident the benefits of cardio-respiratory physiotherapy techniques such as deep breathing exercises and early mobilization, and both groups benefitted from the inclusion of these practises.

**Risks and Benefits**

Risk for participant: Participants were informed that they would not receive any monetary payment for their participation in the trial. An additional 20 minutes was necessary to complete the pre-operative session to gain baseline information. Participants allocated to the treatment group also received a logbook and asked to self-administer the device and complete the Blow Bottle logbook. An additional five minutes was required to obtain spirometry readings daily. Participants were made aware of the risk that spirometry testing might result in some exhaustion, as it required the participant to breathe deeply and exhale rapidly. Once participants were able to mobilize adequately and their chests were clear (ability to clear secretions if any, and no signs of respiratory complications), the physiotherapist assessed the participant and discharged them from physiotherapy. Evaluation by the researcher continued until the patient was discharged from physiotherapy. Participants were made aware of these points within the information sheet and verbal discussion.

**Informed Consent**

When patients were approached pre-operatively, they were given an information letter and asked whether or not they would like to participate in the trial (see Appendix H). The information sheet informed the patient of the study and explained that refusing to participate in the study, would not

affect the treatment they receive in hospital or the routine post-operative cardio-respiratory physiotherapy treatment they received. Only consenting participants were included in the trial. During the pre-operative session, the research personnel obtained written informed consent (see Appendix I). Approaching the participants pre-operatively was to ensure that the participant was not under duress. Verbal consent remained continuous throughout their participation in the trial.

## **CHAPTER 3: RESULTS**

### **3.1 Introduction**

This chapter will describe the profile as well as the outcomes obtained from the total population sampled. The trial initially commenced within the private sector. Despite the inclusion of two private hospitals, no eligible participants were recruited and enrolled from these facilities as no participants met the inclusion criteria during the period of 01 April to 30 June 2014. The results are therefore representative of the population sampled from the public tertiary institution for the period of August to November 2014. This chapter will first report on demographic data, followed by results pertaining to the two objectives previously described in the introduction, which were the effects on lung function and the development of PPCs.

### **3.2 Demographic data of the total sample**

The researcher recruited 24 participants who met the inclusion criteria and were eligible for the trial from the public tertiary institution. Of the 24 participants recruited, five participants were excluded (four participants were excluded as their surgeries were cancelled and one participant was excluded as they remained ventilated for more than 24 hours after surgery), thus leaving a total sample of 19 participants for analysis. All participants underwent general anaesthesia and midline open abdominal surgery. However, the exact duration of surgery and anaesthesia was not recorded on the A-APODS. The median age in years of participants was 53, with a wide age spread from 25 to 84 years. The majority of participants were female (n=14). More than half of the population (n=10) had a history of hypertension and six participants were smokers. Notably, the majority of participants n=15 (79%) were previously admitted for abdominal surgery and approximately half of the total population (n=9) were admitted to have surgery due to cancer. Participants stayed a median of eight days in hospital (as calculated from admission the day prior to surgery) and had a median of four post-operative cardio respiratory sessions (see Table 2). Results depicted that the majority of participants remained for the first and second post-operative days (n=19). Thereafter, participants exited the trial as they were discharged from cardio-respiratory physiotherapy, with 16 participants remaining a third post-operative day, 12 remaining a fourth post-operative day, and 10 remaining a fifth.

**Table 2: Descriptive statistics for the study sample (n=19)**

Variable	Descriptive Statistics		
	All [19] median (range)	Control Group (CG) [11] median (range)	Intervention Group (IG) [8] median (range)
<b>Participant Demographics:</b>			
Age	53 (25-84)	48 (25-68)	59 (45-84)
Sex (Male)*	5	2	3
Sex (Female)*	14	9	5
Weight	69 (50-94)	68 (50-94)	72.4 (57-88)
Height	160.8 (145-183)	160 (145-170)	161.4 (152-183)
Number of cardio-respiratory physiotherapy sessions	4 (2-15)	3 (2-15)	4 (2-12)
Length of hospital stay	8 (5-34)	8 (5-34)	10 (6-20)
<b>Co-morbidities:</b>			
Diabetes*	3	2	1
Hypertension*	10	5	5
COPD*	1	0	1
Asthma*	2	1	1
Smoker*	6	2	4
Previous abdominal surgery*	15	9	6
<b>Type of Surgery:</b>			
Abdominal/peritoneal resection of the rectum*	1	1	0
Cholecystectomy*	4	2	2
Closure of colostomy*	2	2	0
Cystectomy*	2	2	0
Hemicolectomy*	3	1	2
Hepatectomy*	1	1	0
Hernia repair*	1	1	0
Sigmoidectomy*	1	0	1
Transmesenteric resection of the rectum*	4	1	3
<b>Reason for Surgery:</b>			
Bowel obstruction*	1	0	1
CA colon*	4	2	2
CA liver*	1	1	0
CA rectum*	4	1	3
Colostomy post perforated bowel*	2	2	0
Gall stones*	4	2	2
Hernia*	1	1	0
Hydatic cysts*	1	1	0
Pancreatic cysts*	1	1	0
*data reported as total observed cases			

### 3.2.1. Description of the Control Group (CG) and Intervention Group (IG)

Participants were randomized into the CG and IG, resulting in a CG consisting of 11 participants and an IG of 8 participants. The median age of the respective groups was 48 years (CG) and 59 years (IG). Despite the dissimilarity in median age between the CG and IG, no statistically significant difference ( $p>0.05$ ) was found. There were more females in the CG ( $n=9$ ) compared to five in the IG. A large



percentage of the total population had hypertension but was equally spread across the CG and IG. Six participants were smokers, two in the CG and four in the IG. Participants in the CG stayed a median of eight days in hospital compared to the median of 10 days spent by the participants in the IG. Although the median length of stay was slightly longer in the IG, this was found not to be statistically significant. The median range of hospital stay varied between the CG and IG (5-34 days in the CG compared to 6-20 days in the IG). Although the median range of hospital stay was wider in the CG compared to the IG, this too was found not to be statistically significant. Both the CG and IG received conventional post-operative physiotherapy consisting of a combination of deep breathing exercises, manual techniques, and mobilization. The participants in the IG received the additional use of the Blow Bottle. Participants used the Blow Bottle a minimum of ten repetitions during the physiotherapy session as recorded by the treating physiotherapists using the A-APODS. The Blow Bottle logbook was used to record the compliance with the use of the Blow Bottle outside of the physiotherapy session. However, this was poorly adhered to during the study, with only one logbook partially completed. Participants were discharged from physiotherapy once they were able to mobilize independently and their lungs deemed clear.

When looking at the restoration of mobility scoring across the first three post-operative days as recorded on the A-APODS, the following was evident (Table 3): On the first post-operative day, 11 participants (six in the CG and five in the IG), were unable to mobilize out of bed on the first post-operative day. By the second post-operative day, four participants in the CG were unable to mobilize out of bed, but a larger proportion of participants across CG and IG were able to mobilize with standby assistance or independently. By the third post-operative day, three participants were discharged from physiotherapy and majority of the remaining participants were mobile. Reasons for inability to mobilize were however not recorded. Participants in the CG received a median of three cardio-respiratory physiotherapy sessions compared to a median of four sessions received by the IG. The range of cardio-respiratory physiotherapy sessions received across the CG and IG was widespread, but did not vary considerably between groups with a median range of 2-12 sessions received across the CG and 2-15 sessions across the IG. The ratio of participants in the CG and IG remained relatively even across the duration of the study despite the dropout ratio. However, as majority of the participants only remained for the first three post-operative days, comparative analyses across the CG and IG were conducted for a period commencing pre-operatively and across the first three post-operative days.

**Table 3: Mobility indicators for the CG and IG across the first three post-operative days**

	Day 1			Day2			Day 3		
	All (n=19)	CG (n=11)	IG (n=8)	All (n=19)	CG (n=11)	IG (n=8)	All (n=16)	CG (n=9)	IG (n=7)
Unable to mobilize out of bed	11	6	5	4	4	0	2	1	1
Sitting out of bed in chair	4	2	2	5	2	3	2	2	0
Mobile with stand-by assistance	4	3	11	6	2	4	7	3	4
Mobile with no assistance	0	0	0	4	3	1	5	3	2

### 3.3 Lung Function for the Control Group (CG) and Intervention Group (IG)

Lung Function parameters FEV<sub>1</sub> and FVC were recorded across both CG and IG. The median predicted FEV<sub>1</sub> and FVC values were comparable to the median pre-operative FEV<sub>1</sub> and FVC recorded across both CG and IG. Interestingly, although not statistically significant, the median FVC values measured for the IG seemed to drop from day-to-day across the first three post-operative days. The same trend was not evident across the CG (see Table 4). In both groups, the median FEV<sub>1</sub> showed marginal improvements post-operatively but did not significantly differ across groups. Therefore, the improvements in lung function could not be owed specifically to the additional use of the Blow Bottle in the IG. Specific lung function measurements obtained by participants were further analysed and are described below for the CG and IG.

**Table 4: Summary of Lung Function data**

	Lung Function Results		
	All [n=19]	Control Group (CG) [n=11]	Intervention Group (IG) [n=8]
Variable	median (range)	median (range)	median (range)
<b>FEV<sub>1</sub> (L)</b>			
Predicted	2.52 (1.43-3.93)	2.7 (1.43-3.86)	2.52 (1.43-3.93)
Pre-operative	2.58 (1-3.81)	2.56 (1.73-3.13)	2.7 (1-3.81)
Day 1	0.99 (0.44-2.22)	0.88 (0.44-1.7)	1.15 (0.79-2.22)
Day 2	1.21 (0.53-2.16)	1.12 (0.53-2.03)	1.37 (0.9-2.16)
Day 3	1.42 (0.45-1.99)	1.31 (0.45-1.89)	1.55 (0.63-1.99)
<b>FVC (L)</b>			
Predicted	2.82 (1.77-4.9)	2.92 (1.77-4.59)	2.82 (1.77-4.9)
Pre-operative	3.07 (1.11-4.98)	2.91 (2.35-4.51)	3.18 (1.11-4.98)
Day 1	1.62 (0.61-2.91)	1.08 (0.6-2.26)	2.29 (1.11-2.91)
Day 2	1.61 (0.53-3.12)	1.44 (0.53-3.12)	1.99 (1.48-3.04)
Day 3	1.6 (0.45-3.04)	1.6 (0.45-3.04)	1.49 (0.63-2.14)

#### 3.3.1. Lung Function findings for the Control Group (CG)

Lung function measurements were obtained pre-operatively for the CG (n=11). There was missing data across FEV<sub>1</sub> and FVC post operatively. The missing data were due to participants' inability to

perform the manoeuvre required to conduct the spirometry testing because they were either drowsy or hindered by nausea or pain. Findings revealed that there was a statistically significant ( $p<0.05$ ) drop in both FEV<sub>1</sub> and FVC measurements obtained pre-operatively and post-operatively. However, lung function parameters seemed to increase incrementally across the first three post-operative days, except for three participants whose lung function measurements for both FEV<sub>1</sub> and FVC dropped across the post-operative period. Tables 5 and 6 depict these findings where participants who exhibited a decline in lung function measurements are highlighted.

**Table 5: CG FVC pre-operatively and across the first three post-operative days**

	<b>Pre-operative: n=11</b>			<b>Day 1: n=9</b>		<b>Day 2: n=11</b>		<b>Day 3: n=9</b>	
<b>CG (n=11)</b>	<b>Predicted FVC</b>	<b>Pre-operative: FVC</b>	<b>% of Predicted FVC</b>	<b>FVC</b>	<b>% of Pre-operative FVC</b>	<b>FVC</b>	<b>% of Pre-operative FVC</b>	<b>FVC</b>	<b>% of Pre-operative FVC</b>
1	2.4	2.91	121%	0.85	35%	0.55	23%	0.45	19%
2	1.77	2.69	152%	2.04	115%	1.23	69%	3.04	172%
3	2.82	2.35	83%	0.76	27%	1.12	40%	Discharged	Discharged
4	3.91	2.85	73%	1.08	28%	1.51	39%	Discharged	Discharged
5	2.73	3.57	131%	0.61	22%	0.94	34%	1.28	47%
6	4.59	3.16	69%	Missing	Missing	1.48	32%	2.14	47%
7	3.25	3.8	117%	2.26	70%	3.12	96%	1.97	61%
8	3.33	4.51	135%	1.63	49%	2.23	67%	2.42	73%
9	2.92	2.36	81%	1.72	59%	1.92	66%	1.6	55%
10	3.11	3.05	98%	0.73	23%	1.44	46%	1.54	50%
11	2.51	2.79	111%	Missing	Missing	0.53	21%	1.36	54%

**Table 6: CG FEV1 pre-operatively and across the first three post-operative days**

	Pre-operative: n=11			Day 1: n=9		Day 2: n=11		Day 3: n=9	
CG (n=11)	Predicted FEV1	Pre-operative: FEV1	% of Pre-operative FEV1	FEV1	% of Pre-operative FEV1	FEV1	% of Pre-operative of FEV1	FEV1	% of Pre-operative FEV1
1	2.82	2.58	91%	0.75	27%	0.55	20%	0.45	16%
2	1.43	2.32	162%	0.88	62%	1.15	80%	1.54	108%
3	2.4	2.34	98%	0.75	31%	1.05	44%	Discharged	Discharged
4	3.14	2.33	74%	0.98	31%	1.11	35%	Discharged	Discharged
5	2.29	2.79	122%	0.44	19%	0.62	27%	1.22	53%
6	3.86	2.73	71%	Missing	Missing	1.18	31%	1.89	49%
7	2.82	3.13	111%	1.7	60%	2.03	72%	1.77	63%
8	2.87	2.82	98%	1.26	44%	1.44	50%	1.64	57%
9	2.52	1.73	69%	1.16	46%	1.37	54%	1.13	45%
10	2.7	2.56	95%	0.64	24%	1.12	41%	1.31	49%
11	2.1	2.12	101%	Missing	Missing	0.53	25%	1.31	62%

### 3.3.2. Lung Function findings for Intervention Group (IG)

Lung function measurements were obtained pre-operatively for the IG (n=8). The predicted lung function parameters were similar to those obtained pre-operatively except for participant one who only obtained 40% of the predicted FVC and 47% of the predicted FEV<sub>1</sub>. As for the CG, missing data was evident as participants were either drowsy, nauseous or in pain. Similar to the CG, findings revealed that there was a statistically significant ( $p<0.05$ ) drop in both FEV<sub>1</sub> and FVC measurements obtained pre-operatively and post-operatively. Generally, lung function parameters seemed to increase incrementally across the first three post-operative days; however, more participants in the IG seemed to show a drop in post-operative lung function parameters. Four participants exhibited a drop in post-operative FVC measurements and three a drop in FEV<sub>1</sub> measurements. Tables 7 and 8 depict these findings where participants who exhibited a decline in lung function measurements are highlighted.

**Table 7: IG FVC pre-operatively and across the first three post-operative days**

	Pre-operative: n=8			Day 1: n=7		Day 2: n=7		Day 3: n=6	
IG (n=8)	Predicted FVC	Pre-operative: FVC	% of Predicted FVC	FVC	% of Pre-operative FVC	FVC	% of Pre-operative FVC	FVC	% of Pre-operative FVC
1	2.75	1.11	40%	1.11	40%	1.72	63%	1.3	47%
2	2.72	3.41	125%	2.29	84%	1.74	64%	2.02	74%
3	4.15	3.56	86%	2.45	59%	2.19	53%	1.69	41%
4	3.32	3.07	92%	1.61	48%	1.48	45%	2.14	64%
5	4.9	4.98	102%	2.91	59%	2.47	50%	1.08	22%
6	2.63	3.26	124%	2.49	95%	3.04	116%	Discharged	Discharged
7	2.18	3.11	143%	1.16	53%	1.99	91%	0.63	29%
8	2.82	2.68	95%	Missing	Missing	Missing	Missing	Missing	Missing

**Table 8: IG FEV1 pre-operatively and over the first three post-operative days**

	Pre-operative: n=8			Day 1: n=7		Day 2: n=7		Day 3: n=6	
IG (n=8)	Predicted FEV1	Pre-operative: FEV1	% of Predicted FEV1	FEV1	% of Pre-operative FEV1	FEV1	% of Pre-operative FEV1	FEV1	% of Pre-operative FEV1
1	2.11	1	47%	1	47%	1.37	65%	1.09	52%
2	2.32	2.71	117%	2.07	89%	1.62	70%	1.83	79%
3	3.19	2.92	92%	2.22	70%	1.93	61%	1.42	45%
4	2.65	3.81	144%	0.79	30%	1.25	47%	1.99	75%
5	3.93	3.62	92%	0.96	24%	0.9	23%	1.68	43%
6	2.23	2.55	114%	1.28	57%	2.16	97%	Discharged	Discharged
7	1.54	2.7	175%	1.15	75%	1.36	88%	0.63	41%
8	2.39	2.43	102%	Missing	Missing	Missing	Missing	Missing	Missing

### 3.3.3. Lung Function findings across groups

Data for lung function parameters ( $FEV_1$  & FVC) was found to be normally distributed as investigated using P-plots and no difference in variance between CG and IG was found using the Levene's test. Lung function parameters were analysed using the ANOVA and post-hoc Tukey analysis for differences across the CG and IG pre-operatively as well as over the first three post-operative days. No significant difference between the CG and IG ( $n=19$ ) in terms of  $FEV_1$  and FVC across the pre-operative and post-operative days was found. As previously described, a significant difference ( $p<0.05$ ) between pre-operative and post-operative  $FEV_1$  and FVC was found across both the CG and IG ( $n=19$ ). These findings are graphically depicted below in Figure 2 for  $FEV_1$  and Figure 3 for FVC.

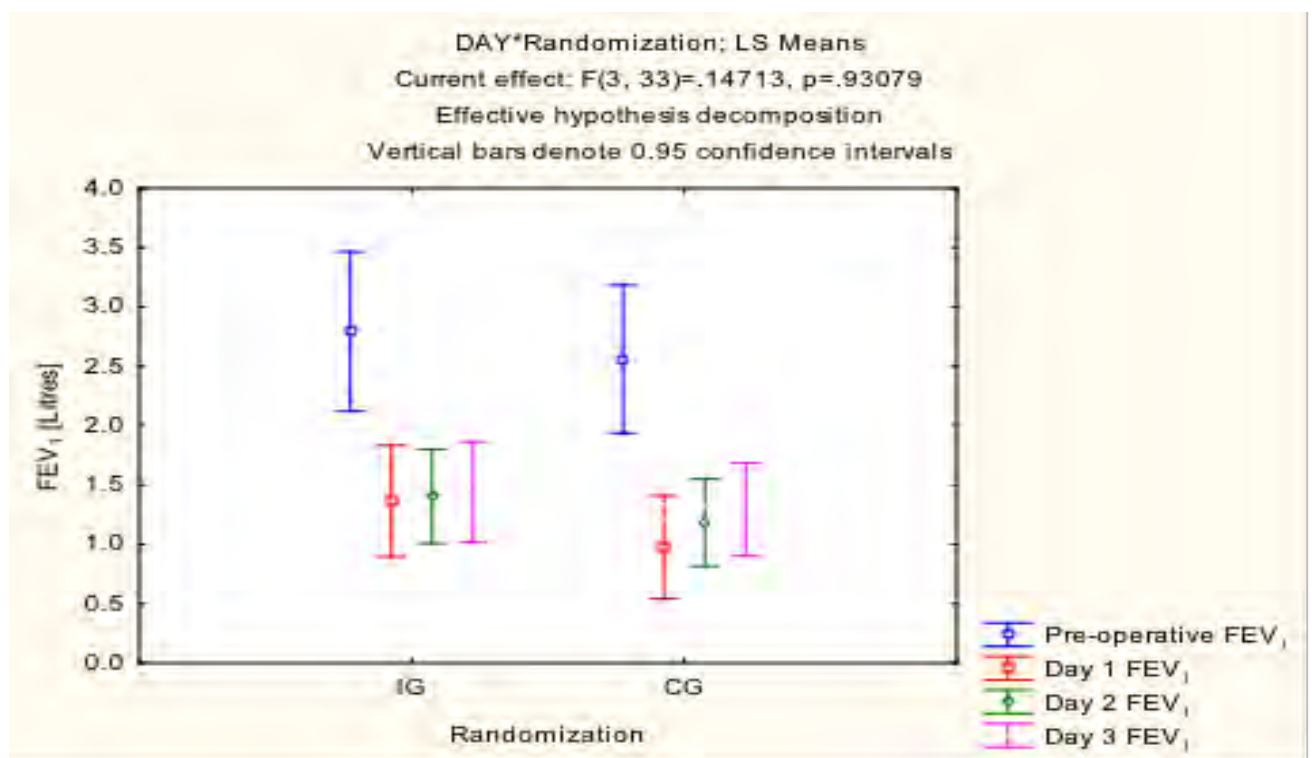


Figure 2: Forced Expiratory Volume in 1 second ( $FEV_1$ ) of 19 participants plotted as means with standard deviation across randomization group (IG versus CG) with the effect of time illustrated within the key. The only statistical differences recorded were between pre-operative and post-operative measures (ANOVA,  $p<0.05$ ), with no effect of randomisation.

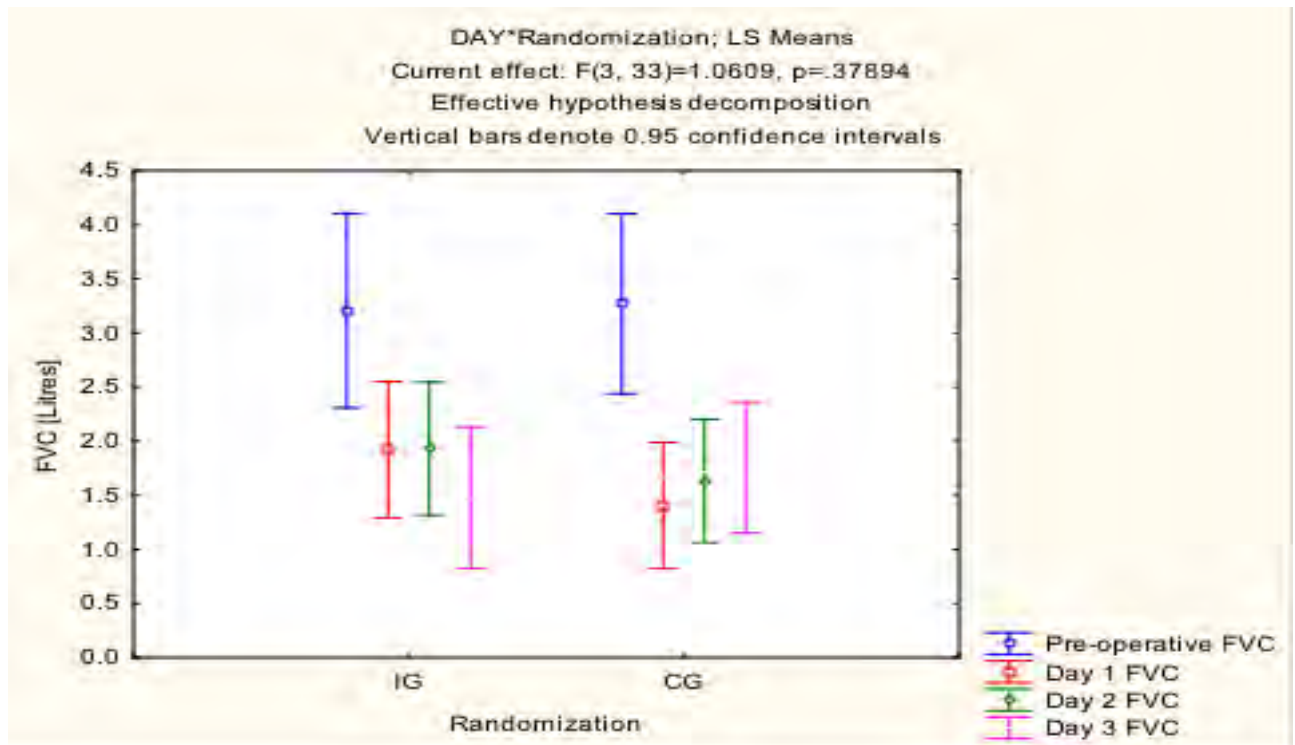


Figure 3: Forced Vital Capacity (FVC) of 19 participants plotted as means with standard deviation across randomization group (IG versus CG) with the effect of time illustrated within the key. The only statistical differences recorded were between pre-operative and post-operative measures (ANOVA,  $p<0.05$ ), with no effect of randomisation.

### 3.4 Post-operative Pulmonary Complications (PPCs)

The criteria for the development of PPCs by Mackay et al. (2005) used for this study necessitated that three or more changes of the four variables auscultation, temperature, X-rays, and sputum were to be present on the same post-operative day in order to diagnose a PPC. No participant had three or more of the variables defined on any one day during the study, hence no participant was described as having developed a PPC according to the above criteria. Sub-analysis of the composite variables was therefore undertaken to investigate changes for each variable component of PPC. Pre-operatively, all participants ( $n=19$ ) had normal breath sounds on auscultation, normal temperature, normal X-rays, and no sputum. Post-operative findings were recorded using the A-APODS and will be further described for each composite variable across the groups.

#### 3.4.1. Auscultation

The A-APODS describes auscultation in terms of four categories: normal breath sounds, decreased breath sounds, minimal crepitation and wheezes, and widespread crepitation and wheezes. Majority of participants ( $n=16$ ) across both groups had decreased breath sounds on the first post-operative day,

which improved over the first three post-operative days. One participant in the CG developed minimal crepitation and wheezes on the second post-operative day. However, across the duration of the study, two participants (one each from CG and IG) developed widespread crepitation and wheezes by the fifth post-operative day. The participant in the CG improved thereafter and had normal breath sounds by the seventh post-operative day. The participant in the IG improved less rapidly and only had normal breath sounds by the 13<sup>th</sup> post-operative day.

### **3.4.2. Temperature**

The A-APODS classifies pyrexia when body temperature is greater than 38°C. On the first post-operative day, one participant from the IG developed a temperature greater than 38°C. One participant from the CG developed a temperature greater than 38°C on the second post-operative day. Across the duration of the study, the two above-mentioned participants spiked temperatures again by the eighth post-operative day.

### **3.4.3. X-ray Changes**

Participants did not have routine daily Chest X-rays, but were rather referred for further imaging investigations, either chest X-Ray or CT, if they became symptomatic. Two participants in the CG developed PPCs diagnosed on CT scan; pleural effusion with atelectasis and bibasilar atelectasis with pneumonia on day two and day five respectively. One participant in the IG developed right basal atelectasis on the fifth post-operative day.

### **3.4.4. Sputum**

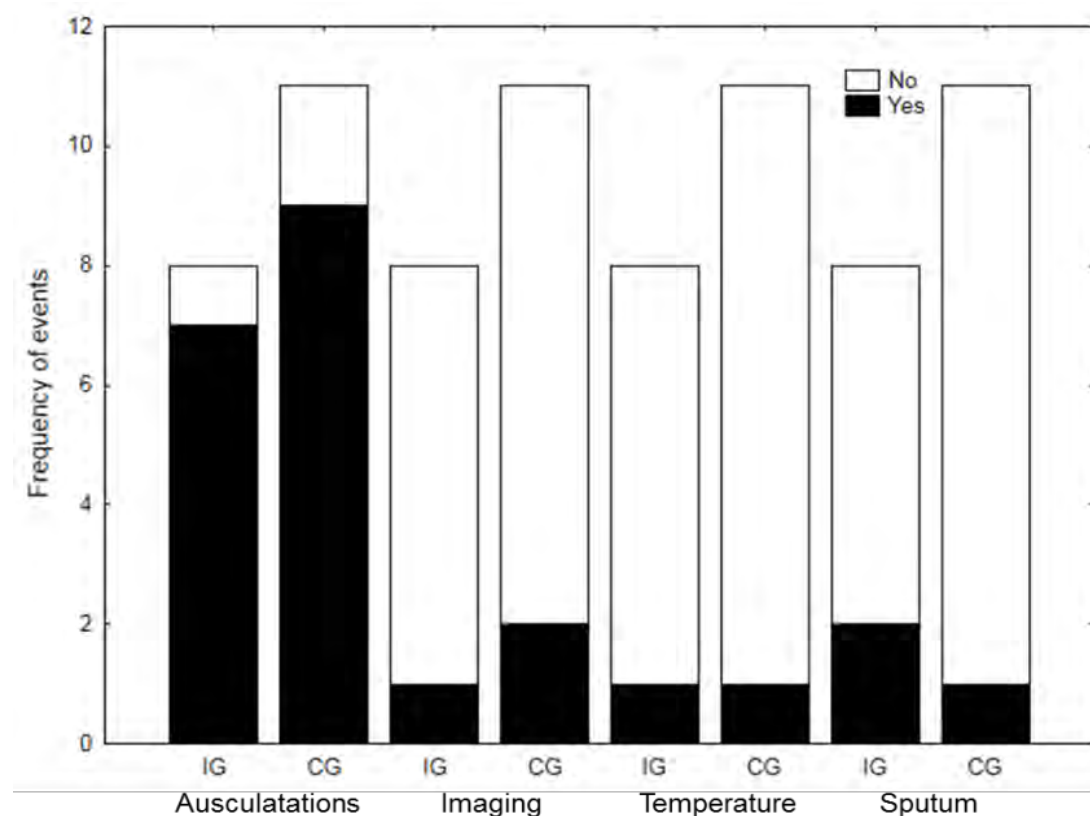
The A-APODS describes sputum changes in terms of four categories: no sputum, small amount (1-2 tsp), moderate amount (up to ¼ cup), and large amount (greater than ¼ cup). No participant in the CG or the IG reported any sputum changes from their pre-operative findings over the first three post-operative days. One participant in the IG developed sputum changes on the fourth post-operative day, producing a small amount of purulent sputum. This increased to a moderate amount on the fifth post-operative day and a large amount by the sixth post-operative day. These sputum findings only dissipated by the twelfth post-operative day. No other participant exhibited sputum changes for the duration of their hospital stay.

### **3.4.5. Summary of Composite PPC findings**

Overall changes in the composite PPC variables from the pre-operative findings were summarized and classified as either being present (yes) or not present (no). This was measured across both CG and



IG for the duration of the study. For example, if a participant exhibited any changes in auscultation findings during the study, this would be depicted as a “yes”. Changes from pre-operative findings were analysed using the Chi-squared test and are depicted graphically in the histogram below (Figure 4). There was no significant difference in findings in each variable between the CG and IG. As previously described, majority of both the CG and IG exhibited changes in auscultation findings relative to pre-operative auscultation findings. Two participants exhibited temperature changes above 38°C. Three were referred for investigative imaging which reported pneumonia and atelectasis, and exhibited changes in sputum relative to pre-operative findings. The three participants, who were referred for investigative imaging, were the same participants who either had changes observed in one of the following, auscultation, temperature, or sputum. None of the participants had three or more of the four aspects occurring simultaneously within the same post-operative day as per the criteria for the development of PPCs by Mackey et al. (2005).



**Figure 4: Changes from the pre-operative findings being present (yes) or not present (no) across composite variables of PPC (auscultation, imaging, temperature, and sputum) for CG and IG across the duration of the study.**

### 3.5 Summary of Results

The total sample obtained (n=19) were majority female, with a wide age range, commonly presented with HPT as comorbid disease, and were admitted previously for abdominal surgery. Reasons for current surgery related to various cancers (see Table 2). Participants received a median of four

physiotherapy sessions and stayed a median of eight days in hospital. Although participants verbally said they used the Blow Bottle outside of the physiotherapy session, there was poor adherence to the use of the Logbook. Majority of participants were unable to mobilize out of bed on the first post-operative day, but progressed daily and were independently mobile by discharge from physiotherapy. Predicted lung function parameters were comparable to the pre-operative lung function parameters measured across both CG and IG. Only one patient in the IG presented with low FEV<sub>1</sub> and FVC pre-operatively, all other patients predicted lung function parameters. No significant difference between the CG and IG in terms of FEV<sub>1</sub> and FVC was observed across both pre-operative and post-operative days. However, a significant difference between pre-operative and post-operative FEV<sub>1</sub> and FVC was found across both groups. None of the participants developed a PPC according to the composite PPC criteria. However, on sub-analysis of each composite variable, participants across both the CG and IG exhibited changes in auscultation findings relative to the pre-operative auscultation findings. Notably, three participants exhibited investigative imaging changes indicative of either pneumonia or atelectasis.

## **CHAPTER 4: DISCUSSION**

### **4.1 Introduction**

This single blinded randomized control trial investigated the use of the Blow Bottle as an adjunct to cardio-respiratory physiotherapy in the post-abdominal surgical population, within institutions in the Western Cape. This chapter will discuss the findings within the context of current literature in relation to the selected objectives:

- Demographic information
- Lung function
- Post-operative pulmonary complications

### **4.2 Demographics**

The median age of the study population was 53 years of age. Studies show that patients over the age of 59 years, who are admitted for surgery, are considered high risk for the development of PPCs (Silva, Li & Rickard, 2012; Mackay, Ellis & Johnston, 2005). Specifically, participants in the IG (n=8) were older than those in the CG (n=11), with an age range of 45 to 84 years, compared to 25 to 68 years in the CG, which places the IG closer to the high risk category. Age has been considered a risk factor for the development of PPCs, as the natural progression of the body leads to decreased perfusion and oxygenation of the tissue, decreased elasticity of the lung tissue, and increased rigidity of the chest wall (Kanonidou & Karystianou, 2007; Sprung, Gajic & Warner, 2006). These factors lead to poor lung compliance and reduced lung function due to the reduced pulmonary compliance (Kanonidou & Karystianou, 2007). However, in the study by Smetana (1999) who evaluated pre-operative pulmonary function found that age alone was not a determinant factor for the development of PPCs but rather the presence of co-morbidities such as COPD, cardiac disease, diabetes, high cholesterol, and hypertension (Smetana, 1999). Co-morbidities are more frequent within the elderly, although the overall health of the patient independent of age is considered when determining whether the patient will be able to successfully undergo surgery (Canet & Mazo, 2010; Smetana, 1999).

Although not statistically significant ( $p > 0.05$ ), having older patients in the IG could have impacted on their post-operative recovery and outcomes of lung function and the development of PPCs. Due to the small sample size of this current study, correlations with age and development of PPCs were not ascertained, as the study lacked power. Co-morbidities in the current study ranged from hypertension, previous abdominal surgery, and cancer. Although not matched from the outset of the study for co-morbidities, the CG and IG had similar co-morbidity profiles. Studies investigating pre-operative risk factors in patients scheduled to undergo abdominal surgery, rated patients with more than one co-morbidity at higher risk for the development of PPCs (Hal et al., 1991). Regarding gender, the

majority participants were female as seen in demographic data depicted in Table 2 (refer 3.2). These findings are in keeping with the scant literature related to abdominal surgery where most participants enrolled were female (Manzano et al., 2008; Mackay, Ellis & Johnston, 2005; Fagevik Olsén et al., 1997; Hall, Tarala, Tapper & Hall, 1996; Hall et al., 1991). In none of the referenced articles above was there a correlation between gender and an increased risk for the development of PPCs in abdominal surgery patients. This is similar in the current study sample. In conclusion, the profile of participants enrolled in the current study was similar to earlier research where the majority participants were female (Manzano et al., 2008; Mackay, Ellis & Johnston, 2005; Fagevik Olsén et al., 1997; Hall et al., 1996; Hall et al., 1991) and admitted for cancer related abdominal procedures (Silva, Li & Rickard, 2012; Browning, Denehy & Scholes, 2007).

#### **4.3 Post-operative Pulmonary complications**

One of the objectives was to investigate the effects the additional use of the Blow Bottle had on the development of PPCs and, to determine whether this effect was more beneficial than conventional post-operative cardio-respiratory physiotherapy alone, that is, did the additional use of the Blow Bottle reduce the incidence of PPCs. However, this objective was not met and the researcher attributes it to the criteria used to diagnose the presence of a PPC as described by Mackay et al. (2005). A PPC was deemed present if a patient had a combination of three or more changes in the following: auscultation, temperature, X-rays, or sputum, within the same day, during the first 14 post-operative days.

For this study, none of the participants had three or more changes on the same post-operative day. However, all participants displayed changes in either one or a combination of the aforementioned criteria for the development of a PPC. Most participants exhibited changes in auscultation findings across the first three post-operative days. More specifically, three patients exhibited radiological changes, which were indicative of pneumonia (n=1; IG) and atelectasis (n=2; CG) on day 2 and 5 respectively. Strictly following the criteria as set out by Mackey et al. (2005), these three participants did not develop a PPC as three or more changes did not occur on the same day. Herewith lies the controversy, as there is no standardization for the criteria for the development of a PPC, nor its definition (Conde & Lawrence, 2008; Mackay, Ellis & Johnston, 2005; Smetana, 1999; Lawrence, Dhanda, Hilsenbeck & Page, 1996). The criteria by Mackay et al. (2005) consists of objective measures to define a PPC, such as auscultation, temperature, sputum, and X-ray findings that are obtainable by the physiotherapist and forms part of the physiotherapist's daily assessment. However, the criteria rely on the assumption that X-rays are performed routinely post-operatively. However, as this study was set in a public tertiary institution, X-rays were not done routinely post-operatively

probably due to steps to curtail costs. Thus, this made the use of radiological changes as seen on X-ray as part of the criteria to diagnose a PPC for physiotherapists, problematic.

This was further compounded as the median range of hospital stay varied between the CG and IG (5-34 days in the CG compared to 6-20 days in the IG) with the majority of participants discharged from physiotherapy within 2 to 3 days post-surgery and exited the study. This made comparisons between groups on each individual day statistically challenging. Due to this large drop out after the first three post-operative days, sub-analysis of the composite variables were used to conduct analyses and was recorded as any change that may have occurred across the duration of the study (see 3.4, figure 4). Sub-analysis of the composite PPC variables showed that changes from the pre-operative existed across both groups and across all variables.

Majority of the participants across groups developed changes in auscultation on the first post-operative day. This was comparable to the findings of Mackay et al. (2005), where 60% of participants developed changes in auscultation findings post-operatively. In the current study, the change in auscultation findings exhibited by majority of participants was that of decreased breath sounds. The decreased ability to expand the chest and inspire is widely reported following open abdominal surgery, where the larger incision may lead to diaphragmatic dysfunction (Siafakas et al., 1999; Frazee et al., 1991; Chuter et al., 1990). Breathing at low tidal volumes may lead to the development of passive atelectasis (Kacmarek, Stoller & Heuer, Egans Fundamentals of Respiratory Care, 2013, pp. 904). The incision site and disruption of the abdominal muscles affects the patient's ability to produce a forced expiratory manoeuvre required to cough effectively and remove secretions that may be present (Tzani, Chetta & Olivieri, 2011; Richardson & Sabanathan, 1997; Roussos, 1985). Retention of secretions and mucus plugging can lead to the development in resorption atelectasis and pneumonia (Kacmarek, Stoller & Heuer, Egans Fundamentals of Respiratory Care, 2013, pp. 904).

In this study, three participants developed changes that warranted further imaging investigation. On the second post-operative day, one participant from the CG developed a temperature greater than 38°C and referred for a Chest CT that reported a right pleural effusion and atelectasis. On the fifth post-operative day, two participants, one from the CG and one from the IG, developed abnormal lung sounds on auscultation; these being crepitation and wheezes indicative of pathology. They were referred for Chest CTs that reported atelectasis and possible pneumonia for the participant in the CG and atelectasis for the participant in the IG. The surgical incision site not only negatively affects the respiratory muscles and the patient's ability to breathe deeply and cough effectively, increasing the risk of the development of PPCs, but also causes post-operative pain and hesitation to mobilize

(Tzani, Chetta & Olivieri, 2011; Richardson & Sabanathan, 1997). This may result in participants being hesitant to mobilize post-operatively due to fear of damaging the wound site or possible pain with mobilization (Cheifetz, Lucy, Overend & Crowe, 2010; Browning, Denehy & Scholes, 2007).

In the current study, majority of the participants were unable to mobilize on the first post-operative day and were reliant on assistance from the physiotherapist or nursing staff. This may have led to participants being mobilized less frequently due to human resource constraints. This is in conflict with evidenced based practice that advocates early and frequent mobilization to improve post-operative lung function and thus reduce the development of a PPC (Silva, Li & Rickard, 2012; Cheifetz et al., 2010; Varadhan, Neal, Dejong, Fearon, Ljungqvist, 2010; Browning, Denehy & Scholes, 2007; Mackay, Ellis & Johnston, 2005; Fagevik Olsén et al., 1997).

Due to the large drop out of participants, but more so, as the criteria for the development of a PPC used for the current study proved to be difficult to implement within this public tertiary institution, inferences as to the efficacy of the Blow Bottle to impact or reduce the development of a PPC is inconclusive. Despite the small size, it is more probable that PPCs in this cohort may have been under-diagnosed.

#### **4.4 Lung Function**

In this study, the researcher chose spirometry to ascertain the effect of the Blow Bottle on lung function. In literature evaluating patients following abdominal surgery, spirometry is commonly used as an outcome measure (Mackay, Ellis & Johnston, 2005; Hasuki et al., 2002; Fagevik Olsén et al., 1997; Joris, Kaba & Lamy, 1997). In the current study, pre-operative FEV<sub>1</sub> and FVC measurements were similar across the IG and the CG except for one participant in the IG who had poor pre-operative lung function. Across both CG and IG, there was a drastic decline in FEV<sub>1</sub> and FVC post-operatively. Across the groups, participants had a median drop of approximately 62% in FEV<sub>1</sub> and 47% in FVC on the first post-operative day. A marked drop in lung function post-operatively was also reported in various other studies where reductions in FEV<sub>1</sub> ranged from 33-50% and 20-36% in FVC on the first post-operative day in patients undergoing open abdominal surgery (Yildirim Osman, Serpil, Umit, Ebru, Bulent, Mete & Omer, 2009; Hasuki et al., 2002; Chumillas, Ponce, Delgado & Viciano, 1998; Joris, Kaba & Lamy, 1997).

Various factors may influence the marked drop in lung function from pre-operative to post-operative. The type of surgery and the incision site itself, as previously described, disrupts the respiratory muscles, hindering inspiration and forced expiration (Tzani, Chetta & Olivieri, 2011; Richardson & Sabanathan, 1997; Roussos, 1985). This can be further aggravated by general anaesthesia. Typically the length of general anaesthesia for open abdominal surgery is approximately four hours (Mackay,

Ellis & Johnston, 2005). The application of general anaesthesia affects the patient's lung function as the anaesthetic agents, mechanical ventilation used and the length of anaesthesia contributes to the collapse of alveoli and decreased respiratory muscle tone, which may lead to impaired oxygenation and carbon dioxide reabsorption (Hedenstierna, 2003). These effects may be present for many days post-operatively (Siafakas et al., 1999). In this cohort, poor FEV<sub>1</sub> and FVC measurements were obtained across both CG and IG over the first three post-operative days of this study. This was similar to findings by Osman et al. (2009) and Schauer et al. (1993) where reductions in FEV<sub>1</sub> and FVC after laparotomy were observed on the first post-operative day, only returning to normal pre-operative measurements by the sixth and tenth post-operative days respectively (Yildirim Osman et al., 2009; Schauer et al., 1993).

In the current study, participants were required to use the Blow Bottle a minimum of ten times under the supervision of the physiotherapist. Additionally, participants were also requested to use the Blow Bottle at least ten times every waking hour on their own. The frequency of the self-administered use of the Blow Bottle was to be recorded using the logbook. The nurses were tasked with the duty of reinforcing the use of the Blow Bottle hourly and assist in the completion of the logbook. Participants and nursing staff agreed upon these aspects pre-operatively. Nevertheless, adherence to completing the logbook was very poor amongst participants, implying poor compliance with the self-administration of the Blow Bottle. In the current study, when considering the effects the Blow Bottle had on lung function, there was no statistical difference between lung function findings across the CG and IG. This could be influenced by the poor compliance with the use of the Blow Bottle outside of the physiotherapy sessions. Improvements in FEV<sub>1</sub> and FVC after the third post-operative day was not seen due to the loss of participants after the third post-operative day, because of the small sample size and large drop out after the third post-operative day, limiting analysis.

## **CHAPTER 5: CONCLUSION**

This study set out to determine whether the additional use of the Blow Bottle was more beneficial compared to conventional post-operative cardio-respiratory physiotherapy alone, by evaluating the effects on lung function and assessing the development of PPCs. None of the participants developed a PPC according to the criteria, although, three participants did have imaging findings indicative of the development of a PPC. In this setting, the criteria employed were unable to identify the development of a PPC. A statistically significant marked reduction in lung function parameters FEV<sub>1</sub> and FVC was observed post-operatively with no statistical difference between groups. No conclusions as to the whether the additional use of the Blow Bottle is more beneficial can be drawn due to the small sample size. When using the Blow Bottle as a self-administered treatment, physiotherapists should be aware that patients might not adhere to the regime prescribed and thus reduce the efficacy of the technique. In particular, physiotherapist should be aware of settings with limited or stretched human resources, and how this may influence compliance to requests made for self-treatment. This study re-iterates the large detrimental effect that open abdominal surgery has on not only lung function but also mobility post-operatively. This study also highlights that literature for the use of the Blow Bottle in the abdominal surgical population is scant and outdated, and sorely lacking in the resource constraint South African hospital settings.



## CHAPTER 6: LIMITATIONS AND RECOMMENDATIONS

This study is largely limited by its small sample size. Over the total duration of the study (April 2014 to December 2014), no eligible participants were enrolled from the private sector. The absence of participants enrolled from the private sector can be attributed to several factors. The study took place during a period when fewer open abdominal surgeries were performed, which could be ascribed to surgeons being away from their practices and to laparoscopic procedures being performed more than open abdominal surgeries. Also, within the chosen private institutions, consent to approach patients scheduled for surgery from one surgeon, who predominantly performed open abdominal surgeries, proved fruitless, as he refused to participate in the trial. In South Africa private health care institutions work on the basis of referral to physiotherapist and thus obtaining the required patient population would be impossible without referral from the attending surgeon. Furthermore the small sample size can be attributed to limited timeframe within the constraints of the funding which was only for a two year. Therefor continuing with the data collection process to achieve a minimum sample size was unfortunately not possible. The sample size therefore depicts the total amount of participants that was able to be included given the available time period. Due the slow uptake of patients and time constraints, the sample is therefore not purely heterogeneous, as although it includes only open abdominal surgical patients, they had varying procedures done. It is however recommended that future studies continue data collection for a longer duration or include multiple trial sites in order to achieve the appropriate homogenous sample size and allow for publishable data to be obtained.

The criteria for the development of PPCs employed were also not ideally suited to this research setting. This raises the need for standardized clinical criteria for the development of PPCs (Conde & Lawrence, 2008; Mackay, Ellis & Johnston, 2005; Smetana, 1999; Lawrence et al., 1996).

The researcher used spirometry as an evidenced based objective outcome measure, but this proved difficult, as accurate spirometry testing is reliant on the patient's ability to follow commands, inspire maximally, and forcefully expire. This is hindered following open abdominal surgery (Tzani, Chetta & Olivieri, 2011; Hasuki et al., 2002; Joris, Kaba & Lamy, 1997; Richardson & Sabanathan, 1997; Coelho, de Araujo, Marchesini, Coelho & de Araujo, 1993). This was observed in our cohort with a number of participants struggling to perform adequate inspiration and expiration manoeuvres. Therefore, as evident in this study, spirometry may not be the best measurement for post-operative lung function in the abdominal-surgical population (Hall et al., 1991). In health care settings with limited human resources and cost constraints, other objective measures could be used to evaluate overall lung function such as the Six Minute Walk Test (6MWT) (Cheifetz et al., 2010). However, the efficacy of this test may possibly be compounded by the patient's hesitation to mobilize post-operatively due to pain and fear of damaging the wound (Cheifetz et al., 2010; Browning, Denehy & Scholes, 2007). It is recommended that future studies examining the abdominal surgical population

record details as to why patients were unable to mobilize. A record of pain levels may be beneficial as this may be an influential factor impacting the patients' willingness to mobilize.

In this study, the researcher observed poor compliance with the self-administered use of the Blow Bottle. Visual cues and encouragement from the entire multi-disciplinary team is therefore recommended to promote the efficacy of the device. The need for further research investigating the abdominal surgical field and the use of tools such as the Blow Bottle, especially in the South African hospital setting and population, is highly recommended to improve evidenced based practise. This should ideally involve both private and public health care settings across a wider geographical area to compensate for the difficulty of research within the private health care sector and would benefit from being adequately powered.

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## APPENDICES

### Appendix A: Adapted Abdominal Surgery Physiotherapy Outcomes Data Sheet (A-APODS)

ADAPTED ABDOMINAL SURGERY PHYSIOTHERAPY OUTCOMES DATA SHEET			
<b>PRE-OPERATIVE RECORD</b>			
<i>(TO BE COMPLETED BY RESEARCH TEAM)</i>			
PATIENT NAME:			CODE:
TYPE OF SURGERY SCHEDULED:			
DATE OF SCHEDULED SURGERY:			
TODAY'S DATE:			
NAME OF PHYSIOTHERAPIST:			
<b>DEMOGRAPHIC INFORMATION</b>			
GENDER: MALE/FEMALE <i>(INSERT M OR F)</i>			
DOB:		HEIGHT: cm	
AGE:		WEIGHT: kg	
<b>MEDICAL HISTORY: Y/N</b>			
DIABETES		LIVER DISEASE	
COPD		KIDNEY DISEASE	
EMPHYSEMA		PREVIOUS STROKE	
ASTHMA		HISTORY OF CANCER	
OTHER LUNG DISEASE <i>(SPECIFY)</i>		PREV. ABDOMINAL SURGERY	
OTHER DISORDER <i>(SPECIFY)</i>		PREV. OTHER SURGERY <i>(SPECIFY)</i>	
<b>SMOKING HISTORY</b>			
SMOKER? Y/N		IF YES, CIGARETTES PER DAY?	
WHEN WAS LAST CIGARETTE?			
<b>CURRENT HISTORY</b>			
ANY RESPIRATORY SYMPTOMS WITHIN THE LAST 2 WEEKS?			
ANY CARDIAC SYMPTOMS WITHIN THE LAST 2 WEEKS?			
<b>SPIROMETRY</b>			
FEV1:		FVC:	
<b>AUSCULTATION: TICK IN COLUMN ON RIGHT</b>			
NORMAL BREATHE SOUNDS			
DECREASED BREATHE SOUNDS			
MINIMAL CREPITATION AND WHEEZES			
WIDESPREAD CREPITATION AND WHEEZES			
<b>SPUTUM: TICK IN COLUMN ON RIGHT (2 TICKS)</b>			
NO SPUTUM			
SMALL AMOUNT (1-2tsp)			
MODERATE AMOUNT (UP TO ¼ CUP)			
LARGE AMOUNT (>¼ CUP)			
NO COLOUR (CLEAR/WHITE)			
COLOUR (PURULENT)			
<b>CHEST X-RAY: TICK IN COLUMN ON RIGHT</b>			
NO X-RAY TODAY			

NORMAL	
MINOR UNSPECIFIED CHANGES OR ANY MENTION OF CONSOLIDATION AND/OR ATELECTASIS (SEGMENTALLY OR ONE LOBE)	
PRONOUNCED (BILATERAL OR WHOLE LOBE) CONSOLIDATION/AND OR ATELECTASIS	
<b>COGNITIVE FUNCTION: TICK IN COLUMN ON RIGHT</b>	
ORIENTATED TO TIME/PERSON/PLACE	
DIFFICULTY FOLLOWING DIRECTIONS	
UNABLE TO FOLLOW DIRECTIONS/DECREASED LEVEL OF CONSCIOUSNESS	
<b>MOBILITY INDICATORS: TICK IN COLUMN ON RIGHT</b>	
WALKING WITH ASSISTIVE DEVICE	
MOBILE WITH NO ASSISTANCE	
IMMOBILE	

ADAPTED ABDOMINAL SURGERY PHYSIOTHERAPY OUTCOMES DATA SHEET			
POST-OPERATIVE RECORD			
PATIENT NAME:			CODE:
TYPE OF SURGERY:			
DATE OF SURGERY:	TODAY'S DATE:	POST-OP DAY:	
DATE OF D/C FROM:	PHYSIO:	HOSP:	
ATTACHMENTS			
	INSERT YES OR NO (Y OR N)	IF YES, INSERT TODAY'S VALUE	
STOMA			
DRAIN (SPECIFY)			
NGT (ON DRAINAGE)			
EPIDURAL		NO VALUE REQUIRED	
PCA		NO VALUE REQUIRED	
URINARY CATHETER		NO VALUE REQUIRED	
OTHER (SPECIFY)			
VITALS (PLEASE INSERT VALUES)			
SATURATION: %		OXYGEN: LITRES	
HR:	RR:	BP:	
TEMPERATURE: TICK IN COLUMN ON RIGHT			
<38°C			
38-38.9°C			
39-39.9°C			
>40°C			
AUSCULTATION: TICK IN COLUMN ON RIGHT			
NORMAL BREATHE SOUNDS			
DECREASED BREATHE SOUNDS			

MINIMAL CREPITATIONS AND WHEEZES	
WIDESPREAD CREPITATIONS AND WHEEZES	
<b>SPUTUM: TICK IN COLUMN ON RIGHT (2 TICKS)</b>	
NO SPUTUM	
SMALL AMOUNT (1-2tsp)	
MODERATE AMOUNT (UP TO ¼ CUP)	
LARGE AMOUNT (>¼ CUP)	
NO COLOUR (CLEAR/WHITE)	
<b>CHEST X-RAY: TICK IN COLUMN ON RIGHT</b>	
NO X-RAY TODAY	
NORMAL	
MINOR UNSPECIFIED CHANGES OR ANY MENTION OF CONSOLIDATION AND/OR ATELECTASIS (SEGMENTALLY OR ONE LOBE)	
PRONOUNCED (BILATERAL OR WHOLE LOBE) CONSOLIDATON/AND OR ATELECTASIS	
<b>COGNITIVE FUNCTION: TICK IN COLUMN ON RIGHT</b>	
ORIENTATED TO TIME/PERSON/PLACE	
DIFFICULTY FOLLOWING DIRECTIONS	
UNABLE TO FOLLOW DIRECTIONS/DECREASED LEVEL OF CONSCIOUSNESS	
<b>MOBILITY INDICATORS: TICK IN COLUMN ON RIGHT</b>	
WALKING WITH ASSISTIVE DEVICE	
MOBILE WITH NO ASSISTANCE	
IMMOBILE	
<b>TREATMENT: TICK IN COLUMN ON RIGHT</b>	
MOBILIZATION	
DBE	
FET	
VIBRATIONS	
PERCUSSIONS	
EXERCISE	
OTHER:	
<b>BLOW BOTTLE</b>	
DOES PATIENT HAVE A BB? Y/N	
REPS AND SETS:	
DURATION OF EXPIRATION: <i>IN SECONDS</i>	

## Appendix B: Abdominal Surgery Physiotherapy Outcomes Data Sheet (APODS)

ABDOMINAL SURGERY PHYSIOTHERAPY OUTCOME DATA SHEET version 2

Preoperative data:		Surgeon:	
Patient ID:	Male / Female	Height: cm	Weight: kgs
Language preferred at home:		Date of admission:	
Age:	LOS:	Date of operation:	
History of CAL: (tick if present)		Discharge date:	
Asthma	Years:	Smoker? Yes / No	
Bronchitis	Years:	When was their last cigarette?	
Emphysema	Years:	No. of cigs/day prior to quitting?	
Other	Years:	No. of years the patient has smoked?	
Preop auscultation:		Chest Xray:	
Decreased breath sounds	Yes / No	Abnormal findings:	
Crackles	Yes / No	Details:	
Wheezes	Yes / No		
Bronchial breath sounds	Yes / No		
Other (details):	Yes / No	ASA score:	
History of systemic disease:		Vascular disease/hypertension:	
Pulmonary disease	Years:	History of stroke/ TIA:	
Cardiac disease	Years:	History of cancer:	
Diabetic	Years:	Other/prev operations:	
Liver disease:	Years:		
Kidney dysfunction:	Years:		
Cognitive function: (A) Oriented to person, place, time (B) Difficulty following directions or learning new skills (C) Unable to follow directions / decreased level of consciousness			
Preoperative mobility:			
(I) Patient is independantly mobile over 30 m (with/ without usual aid)			
(S) Mobility is limited by shortness of breath			
(M) Mobility is limited by musculoskeletal problems			
(O) Mobility limited by other (details):			
Aids used: Additional comments:			
Spirometry results: (or attach printout)		Other physio preop interventions:	
Peak Flow:			
MEFR ( 25-75% )			
FEV1			
FVC			
Preop checklist			
Explanation of study and consent			
Randomisation			
Instruction and info sheet re mobilisation and limb x's			
Instruction and info sheet re breathing exercises (if appropriate)			
Assessment completed			
Physio ID	Number of preop OOS	Individual Patient Attributable time (Preop only)	

Treatment time and number of treatments:								
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Individual Patient								
Attributable time in minutes								
No. of treatments								
Physio ID								
	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Individual Patient								
Attributable time in minutes								
No. of treatments								
Physio ID								
<b>Operative Details</b>								
Operation:				Elective/Emergency				
Duration of anaesthetic:				Incision type: Other				
Time in OR:				Midline				
Time out OR:				Upper				
Intraoperative sepsis (pus) at time of operation:				Contaminated				
Clean				Dirty				
Antibiotics: (Days and names)								
Pain medication:				Sedatives:				
PCA, pethidine, morphine				Other:				
Epidural:								
Oxygen: (Postop days):				Humidification (Post op days):				
Mechanical ventilation (postop days):				PaO2 < 80mmHg (post op days):				
Nasogastric tube removed ?				Days in ICU:				
Documented other complications:				Unstable blood pressure				
Postop confusion				Pulmonary embolus				
Bleeding				Deep venous thrombosis				
Drowsiness				Dizziness/fainting				
Inadequate pain relief				Nausea/vomiting				
Other:								
Documented respiratory complications:				Bronchitis				
Atelectasis				Infection				
Pneumonia								
Other:								
Notes								

MHN

Outcomes: Score each respiratory sign as 0 1 2 3

Date	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Auscultation								
Temp								
CXR								
Sputum								

Date	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
Auscultation								
Temp								
CXR								
Sputum								

OUTCOMES CODES:

**Auscultation sounds:**

Definitely **no changes** (compared to preop assessment): Normal breath sounds: 0

Any one (or more) of the following: Decreased breath sounds, wheezes, crackles or adventitious sounds: **recorded once** by physiotherapist or medical: 1

Any one (or more) of the following: Decreased breath sounds, wheezes, crackles or adventitious sounds: **recorded twice** on the same day (at more than 2hr intervals): 2

Any one (or more) of the following: Bronchial BS's, widespread crackles, audible wheeze, no breath sounds, transmitted upper airway noises, audible secretions/rattles: 3

**Sputum, as recorded by the physiotherapist:**

Highest temp in 24 hrs:

< 38°C: 0

38°C to 38.9°C: 1

39°C to 39.9°C: 2

> 40°C: 3

No sputum or small amount clear: 0

Small amount coloured (< 2 tsp yellow/green) or moderate and clear/white: 1

Moderate amount coloured (up to quarter cup/day), large and clear/white: 2

Large amount coloured (> quarter of a cup/day): 3

**Chest x-ray from written report:**

No changes. Normal clear xray or same as preoperative CXR: 0

Minor or basal changes to chest xray, unspecified changes. Any mention of minor atelectasis, consolidation, decreased lung volume, or plate-like atelectasis: 1

Sub-segmental changes as above (less than a whole lobe involvement): 2

Bilateral or lobar changes (whole lobe or more) collapse, consolidation and/or atelectasis: 3

MOBILITY INDICATORS:

1st day sit out of bed

1st day walk

Able to walk 50m with standby assistance by the end of the day

## Appendix C: Blow Bottle Logbook

### BLOW BOTTLE LOGBOOK

#### PHYSIOTHERAPY CLINICAL TRIAL

***TASK: AT LEAST 10 BLOWS, EVERY HOUR***

TIME	NUMBER OF BLOW BOTTLE REPETITIONS	SIGNATURE OF PARTICIPANT	SIGNATURE OF NURSING STAFF (WITNESS)	REASON FOR INCOMPLETION OF THE BLOW BOTTLE TASK (if applicable)
8:00				
9:00				
10:00				
11:00				
12:00				
13:00				
14:00				
15:00				
16:00				
17:00				
18:00				

## Appendix D: Ethical Approval Letter

UNIVERSITY OF CAPE TOWN



Faculty of Health Sciences  
Human Research Ethics Committee  
Room E52-24 Groote Schuur Hospital Old Main Building  
Observatory 7925  
Telephone [021] 406 6338 • Facsimile [021] 406 6411  
e-mail: [shuretta.thomas@uct.ac.za](mailto:shuretta.thomas@uct.ac.za)  
Website: [www.health.uct.ac.za/research/humanethics/forms](http://www.health.uct.ac.za/research/humanethics/forms)

16 August 2013

**HREC REF: 493/2013**

**Ms S Manie**  
Physiotherapy  
Room 24, F56  
OMB

Dear Ms Manie

**PROJECT TITLE: EVALUATION OF POSITIVE EXPIRATORY PRESSURE (PEP) DEVICES AS AN ADJUNCT TO PHYSIOTHERAPY IN PATIENTS FOLLOWING OPEN ABDOMINAL SURGERY**

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

**Approval is granted for one year till the 30<sup>th</sup> August 2014**

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: [www.health.uct.ac.za/research/humanethics/forms](http://www.health.uct.ac.za/research/humanethics/forms))

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

**Please quote the HREC. REF in all your correspondence.**

Yours sincerely

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, FHS HUMAN ETHICS**

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

s.thomas



## Appendix E: Amended and Renewed Ethical Approval Letter

<div style="display: inline-block; vertical-align: middle; text-align: center;"> <p>HUMAN RESEARCH ETHICS COMMITTEE</p> <p>17 JUN 2014</p> <p>HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN</p> </div> <div style="display: inline-block; vertical-align: middle; text-align: center;"> <p>FACULTY OF HEALTH SCIENCES Human Research Ethics Committee</p> </div>	
<p><b>Form PH5003: Protocol Amendment</b></p>	
<p><b>HREC office use only (FWA00001637; IRB00001638)</b></p>	
<input checked="" type="checkbox"/> Approved	<input checked="" type="checkbox"/> Type of review: Expedited <input type="checkbox"/> Full committee
<p>This serves as notification that all changes and documentation described below are approved.</p>	
<p>Signature Chairperson of the HREC</p>	<p>Date</p>
<p><i>[Signature]</i> <i>17/6/2014</i></p>	
<p><small>Note: All amendments should include a Synopsis justifying the changes for the amendment (see notice dated 29 April 2013)</small></p>	
<p><b>Principal Investigator to complete the following:</b></p>	
<p><b>1. Protocol Information</b></p>	
Date form submitted	<i>August 2013 16 June 2014</i>
HREC REF Number	483/2013
Protocol title	Evaluation of Positive Expiratory Pressure (PEP) devices as an adjunct to physiotherapy in patients following abdominal surgery
Protocol number (if applicable)	
Principal Investigator	Frene Jacobs JCBREN005
Department / Office Internal Mail Address	Physiotherapy
1.1 Is this a major or a minor amendment? (see FW500003)	<input type="checkbox"/> Major <input checked="" type="checkbox"/> Minor
1.2 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p><b>2. List of Proposed Amendments with Revised Version Numbers and Dates</b></p>	
<p>Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.</p>	
<p><i>Research Design: Amended to use a repeated measures design.</i>  <i>Sample Size: Amended to use a repeated measures design with 10 employed.</i>  <i>Research Setting: Amended to include Groote Schuur Hospital.</i>  <i>Intervention Methods: Amended.</i>  <i>Randomisation: Amended.</i>  <i>For detailed description, see amended proposal with track changes on page 9 and 10.</i></p>	

## Appendix F: Approval Letter (Life Healthcare)

**ATTENTION: R JACOBS**

### **APPROVAL FOR RESEARCH STUDY**

**TITLE: Evaluation of positive expiratory pressure (PEP) devices as an adjunct to physiotherapy in patients following abdominal surgery.**

Our previous correspondence refers.

The Research Committee of Life Healthcare has granted permission for your study to be conducted within the company's facilities. Please present this letter to the Hospital Manager of each institution when seeking permission to use facilities.

We look forward to seeing the results of your research once it is completed.

Yours sincerely

**Anne Roodt**

**Education Specialist**

**Life** College of Learning

## Appendix G: Approval Letter (Groote Schuur Hospital)



### GROOTE SCHUUR HOSPITAL

Enquiries: Dr Bernadette Eick

E-mail : [Bernadette.Schmitz@westerncape.gov.za](mailto:Bernadette.Schmitz@westerncape.gov.za)

Ms. S. Manie  
Physiotherapy  
Room 24 – F56  
Old Main Building

E-mail: [rene.catherine@gmail.com](mailto:rene.catherine@gmail.com)

Dear Ms. Manie

**RESEARCH PROJECT: Evaluation of Positive Expiratory Pressure (PEP) Devices as an Adjunct to Physiotherapy in Patients Following Open Abdominal Surgery**

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:

- a) Your research may not interfere with normal patient care
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) **No patient folders may be removed from the premises or be inaccessible.**
- e) Please introduce yourself to the person in charge of an area before commencing.
- f) Please discuss the study with Mrs. M. Ross: Head Nursing; Professor D. Kahn: Head Surgery and Ms. Davids: Head Physiotherapy before commencing.
- g) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- h) Confidentiality must be maintained at all times.

I would like to wish you every success with the project.

Yours sincerely

**DR BERNADETTE EICK**  
**CHIEF EXECUTIVE OFFICER**

**Date:** 27<sup>th</sup> June 2014

C.C Mrs M. Ross, Mr L. Naidoo and Professor D. Kahn

G46 Management Suite, Old Main Building,  
Observatory 7925

Tel: +27 21 404 6288 fax: +27 21 404 6125

Private Bag X,  
Observatory, 7935

[www.capegateway.gov.za](http://www.capegateway.gov.za)

## Appendix H: Information Letter

### Evaluation of Positive Expiratory Pressure (PEP) devices as an adjunct to physiotherapy in patients following abdominal surgery



Miss Rene Jacobs  
(in fulfilment of a Physiotherapy Master's Degree by dissertation through the University of Cape Town)

HREC REF: 493/2013  
Student Number: JCBREN005  
Cell: 0827726423  
E-mail: [rene.catherine@gmail.com](mailto:rene.catherine@gmail.com)

#### Information letter

You are invited to participate in a study conducted by Rene Jacobs, in fulfilment of a Physiotherapy Master's Degree through the University of Cape Town. The study is entitled "Evaluation of Positive Expiratory Pressure (PEP) devices as an adjunct to physiotherapy in patients following open abdominal surgery".

#### Purpose of the study:

PEP therapy was developed in Denmark in the 1970's. It includes the use of devices that provide some resistance while you breathe out, and has been shown to assist with improving lung function. For this study, the PEP device that will be used is the Blow Bottle. This is a simple device consisting of a plastic bottle filled halfway with water, with a tube in it. When you blow through this tube, you create a stream of bubbles, and the water acts as resistance. Studies investigating the effectiveness of the Blow Bottle are very old, some dating back to the 70's, however, this device is used commonly in South Africa as it is inexpensive and simple to use. Not enough research on the use of this Blow Bottle device in clinical practise exists, and the benefits of the device have not been properly investigated, especially in patients undergoing abdominal surgery. Physiotherapy after abdominal surgery has shown to benefit patients and has become part of the routine post-operative management of patients undergoing abdominal surgery, but adding the Blow Bottle to physiotherapy treatment has not been properly evaluated. This study serves to add to the existing knowledge about the Blow Bottle, and investigate how useful this device may be when added to a physiotherapy treatment. Findings from this study will hopefully improve physiotherapy in South Africa.

#### Selection of participants:

You have been selected to participate in this study as you have been scheduled for abdominal surgery.

#### Description of the study:

As part of the study, you will also be required to undergo a pre-operative session with the research team. This session serves to get baseline information such as medical history, including a lung function test using a portable lung function-testing machine called a Spirometer. You breathe into a tube 3 times and the machine measures your lung function. The test takes less than 10 minutes to complete. You will be contacted telephonically to arrange this consultation. This session will take no longer than 20 minutes.

This study's format is a Randomized Control Trial (RCT). This means that the participants consenting to be part of the trial will be divided randomly into two groups: one group receiving normal post-operative physiotherapy, and the other group receiving normal post-operative physiotherapy with the additional use of the Blow Bottle. On the first day after your surgery, prior to your first physiotherapy treatment, you will be randomly assigned to a group. Both groups will receive normal physiotherapy, which is the standard care of the hospital. This physiotherapy treatment includes getting out of bed, deep breathing exercises, coughing, and other physiotherapy techniques that will assist in maintaining and improving your lung function and get you back on your feet. The group receiving the Blow Bottle will receive normal physiotherapy, but in their session, they will be asked to use the Blow Bottle device. If you form part of this group, you will be asked to perform the Blow Bottle exercise for 10 blows every waking hour. Participants will be given a logbook to record when they have used the Blow Bottle. The logbook is used to document if you use the Blow Bottle without the physiotherapist, and must be signed off by the nursing staff each time you use the Blow Bottle every hour.

Both groups will be given physiotherapy at least once daily. The physiotherapist will collect daily data from your treatment such as information about your surgery and wound site, the physiotherapy treatment you are receiving, details of any lung or other complications that may or may not happen, how you are mobilizing in the ward, and how long you stay in hospital. This forms part of the general physiotherapy assessment you would have if you were not part of the study, and is documented more specifically for the purposes of this study.

The research team will also come every second day to assess your lung function using the spirometer, starting on the first day you have your surgery until the day you are discharged from physiotherapy or the hospital. This is done exactly how it was done in the pre-operative session. They will come and conduct the lung function test at your bedside.

The research team will be unaware of which group you have been allocated to. Therefore, you are requested to not tell the research team which group you have been allocated to. The study will continue for the time that you spend in hospital or until your physiotherapist deems you suitable to discontinue physiotherapy.

#### Risks and Benefits:

As a participant, you will be required to attend a pre-operative session to retrieve baseline information. You will not be expected to pay for this session, but will also not receive any monetary compensation for this session in terms of time and cover for travelling costs. If you do not consent to participate in this pre-operative session, then you will be excluded from the study. This will by no means affect the physiotherapy you receive or the service provided to you in hospital.

You will be receiving conventional physiotherapy after your surgery. This forms part of the regular practice of the hospital and is the routine care you would receive if you were not part of the study. This means that you are responsible for payment of the physiotherapy services, as per the routine practices of the hospital. Physiotherapy has proven to be beneficial, but can cause exhaustion during the treatment. In addition, physiotherapy includes the use of deep breathing exercises and coughing that might be painful due to the surgical wound. Physiotherapy

after abdominal surgery is routinely given in the hospital setting and is used to reduce the risk of lung infections and improve your function.

Your lung function will be tested by the research team using the lung function machine. This test is less than 10 minutes long, but you should be made aware that this test might cause some exhaustion, as it requires you to breathing deeply and exhale rapidly. This test was shown to not be harmful and the information from these tests are very important for this study.

By being part of this study, you will receive the exact level of care and physiotherapy treatment you would have received if you were not participating in the study. However, by being part of the study, you will allow us to get information so that we can improve the level of care patients receive in hospital.

#### Contact Details:

If you have any queries, or need more information about your rights as a research participant, you may contact Rene Jacobs (primary investigator), Mrs Shamila Manie (Masters Supervisor), or the Health Sciences Human Research Ethics Committee (HREC) of the University of Cape Town.

Primary investigator:	Rene Catherine Jacobs (UCT Masters student)
	0827726423
Supervisor:	Mrs Shamila Manie
	(021) 406-6571
HREC UCT:	Professor Marc Blockman (Chairperson of HREC)
	<u><a href="http://www.health.uct.ac.za">www.health.uct.ac.za</a></u>
	(021) 4066496

## Appendix I: Informed Consent Form

### Evaluation of Positive Expiratory Pressure (PEP) devices as an adjunct to physiotherapy in patients following abdominal surgery



Miss Rene Jacobs  
(in fulfilment of a Physiotherapy Master's Degree by dissertation through the University of Cape Town)

HREC REF: 493/2013  
Student Number: JCBREN005  
Cell: 0827726423  
E-mail: [rene.catherine@gmail.com](mailto:rene.catherine@gmail.com)

### Information regarding study

You are invited to participate in a study conducted by Rene Jacobs, in fulfilment of a Physiotherapy Master's Degree through the University of Cape Town. The study is entitled "Evaluation of Positive Expiratory Pressure (PEP) devices as an adjunct to physiotherapy in patients following open abdominal surgery".

#### Confidentiality:

When information is collected, it will be captured and coded so that you remain anonymous. This data will be given to the primary researcher, Rene Jacobs and put in the Masters Thesis. This data will form part of articles that will hopefully be published in a health science journal.

#### What if Something Goes Wrong?

The University of Cape Town (UCT) undertakes that in the event of you suffering any significant deterioration in health or well-being, or from any unexpected sensitivity or toxicity that is caused by your participation in the study, it will provide immediate medical care. UCT has appropriate insurance cover to provide prompt payment of compensation for any trial-related injury according to the guidelines outlined by the Association of the British Pharmaceutical Industry, ABPI 1991. Broadly speaking, the ABPI guidelines recommend that the insured company (UCT), without legal commitment, should compensate you without you having to prove that UCT is at fault. An injury is considered trial-related if, and to the extent that, it is caused by study activities. You must notify the study doctor immediately of any side effects and/or injuries during the trial, whether they are research-related or other related complications.

UCT reserves the right not to provide compensation if, and to the extent that, your injury came about because you chose not to follow the instructions that you were given while you were taking part in the study. Your right in law to claim compensation for injury where you prove negligence is not affected. Copies of these guidelines are available on request.

You are free to not participate in the study, or stop participating at any point. This will in no way affect your hospital stay, your physiotherapy treatment, or the level of hospital care you receive. You are also not obligated to give an explanation for the above.

Statement of Consent:

I have read the above information and the information contained within the information letter. I have asked questions and have received answers. I understand the meaning of confidentiality. I understand that I have the right to refuse to participate in the study.

I consent to participate in the study.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of primary investigator:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Contact Details:

If you have any queries, or need more information about your rights as a research participant, you may contact Rene Jacobs (primary investigator), Mrs Shamila Manie (Masters Supervisor), or the Health Sciences Human Research Ethics Committee (HREC) of the University of Cape Town.

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